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## DELTA REPORT

10-Q

VERU - VERU INC.

10-Q - DECEMBER 31, 2022 COMPARED TO 10-Q - JUNE 30, 2022

The following comparison report has been automatically generated

**TOTAL DELTAS** 1628

■ CHANGES	231
■ DELETIONS	1074
■ ADDITIONS	323

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **June 30**, 2022

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number 1-13602

**Veru Inc.**

(Exact Name of Registrant as Specified in its Charter)

Wisconsin  
(State of Incorporation)

39-1144397

(I.R.S. Employer Identification No.)

2916 N. Miami Avenue, Suite 1000, Miami, FL  
(Address of Principal Executive Offices)

33127

(Zip Code)

305-509-6897  
(Registrant's Telephone Number, Including Area Code)

N/A

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	VERU	Nasdaq Capital Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as determined by Rule 12b-2 of the Exchange Act). Yes  No

As of **August 8, 2022** **February 6, 2023**, the registrant had **80,146,735** **80,657,019** shares of \$0.01 par value common stock outstanding.

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FORWARD LOOKING STATEMENTS

Certain statements included in this quarterly report on Form 10-Q which are not statements of historical fact are intended to be, and are hereby identified as, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the anticipated or potential impact of COVID-19 and the global response thereto on our financial condition or business, our development and commercialization plans relating to our product candidates and products, including any potential commercialization of sabizabulin for certain COVID-19 patients, future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, royalty payments, outcome of contingencies, financial condition, results of operations, liquidity, cost savings, future ordering patterns of our customers, objectives of management, business strategies, clinical trial timing, plans and results, the achievement of clinical and commercial milestones, the advancement of our technologies and our products and drug candidates, and other statements that are not historical facts. Forward-looking statements can be identified by the use of forward-looking words or phrases such as "anticipate," "believe," "could," "expect," "intend," "may," "opportunity," "plan," "predict," "potential," "estimate," "should," "will," "would" or the negative of these terms or other words of similar meaning. These statements are based upon the Company's current plans and strategies and reflect the Company's current assessment of the risks and uncertainties related to its business and are made as of the date of this report. These statements are inherently subject to known and unknown risks and uncertainties. You should read these statements carefully because they discuss our future expectations or state other "forward-looking" information. There may be events in the future that we are not able to accurately predict or control and our actual results may differ materially from the expectations we describe in our forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include the following:

- potential delays in the timing of and results from clinical trials and studies, including potential delays in the recruitment of patients and their ability to effectively participate in such trials and studies, due to COVID-19 or other reasons, and the risk that such results will not support marketing approval and commercialization in the United States or in any foreign country;
- potential delays in the timing of any submission to the U.S. Food and Drug Administration (the "FDA") or any other regulatory authority around the world and potential delays in, or failure to obtain, from any such regulatory authority approval of products under development or authorization of the Company's emergency use authorization application applications for sabizabulin for certain COVID-19 patients, including the risk of a delay or failure in reaching agreement with the FDA on the design of any clinical trial, including any post-approval or post-authorization study, or in obtaining authorization to commence a clinical trial or commercialize a product candidate in the U.S. or elsewhere;
- potential delays in the timing of approval by the FDA approval or any other regulatory authority of the release of manufactured lots of approved products;
- clinical trial results supporting any potential regulatory approval or authorization of any of our products, including sabizabulin for the treatment of certain COVID-19 patients, may not be replicated in clinical practice;
- clinical results or early data from clinical trials may not be replicated or continue to occur in additional trials or may not otherwise support further development in the specified product candidate or at all;
- risks related to our ability to obtain sufficient financing on acceptable terms when needed to fund product development and our operations, including our ability to secure timely grant or other funding to develop, manufacture or distribute sabizabulin as a potential COVID-19 treatment;
- risks related to the development of our product portfolio, including clinical trials, regulatory approvals and time and cost to bring any of our product candidates to market, and risks related to efforts of our collaborators such as in the development of a companion diagnostic for enobosarm;
- risks related to the impact of the COVID-19 pandemic on our business, the nature and extent of which is highly uncertain and unpredictable;
- our pursuit of a COVID-19 treatment candidate is still in development and we may be unable to develop a drug that successfully treats the virus in a timely manner, if at all;
- risks related to our commitment of financial resources and personnel to the development of a COVID-19 treatment which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties about the longevity and extent of COVID-19 as a global health concern and the possibility that as vaccines and other treatments become widely distributed the need for new COVID-19 treatment candidates may be reduced or eliminated;
- risks related to our ability to scale up and manufacture sabizabulin in sufficient quantities as a COVID-19 treatment if we receive an emergency use authorization; authorization in the U.S. or elsewhere;

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- government entities may take actions that directly or indirectly have the effect of limiting opportunities for sabizabulin as a COVID-19 treatment, including favoring other treatment alternatives or imposing price controls on COVID-19 treatments;

- government entities in the U.S. or elsewhere may declare the COVID-19 pandemic emergency over and, if sabizabulin is authorized in the U.S. or elsewhere for the treatment of certain COVID-19 patients under an Emergency Use Authorization or similar regime outside the U.S., such termination of the pandemic emergency may affect our ability to continue to market sabizabulin;
  - product demand and market acceptance of our commercial product products and our products in development, if approved;
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**Table** risks related to our ability to obtain insurance reimbursement from private payors or government payors, including Medicare and Medicaid, for our approved or authorized products, including, if authorized, sabizabulin for the treatment of **Contents**

certain COVID-19 patients, and similar risks relating to market or political acceptance of any potential or actual pricing for any such products;

- some of our products are in development and we may fail to successfully commercialize such products;
- risks related to any potential new telehealth platform developed or used by us in commercializing our current product or potential future products, including potential regulatory uncertainty around such platforms;
- risks related to intellectual property, including the uncertainty of obtaining intellectual property protections and in enforcing them, the possibility of infringing a third party's intellectual property, and licensing risks;
- competition from existing and new competitors including the potential for reduced sales, pressure on pricing and increased spending on marketing;
- risks related to compliance and regulatory matters, including costs and delays resulting from extensive government regulation and reimbursement and coverage under healthcare insurance and regulation as well as potential healthcare reform measures;
- the risk that we will be affected by regulatory and legal developments, including a reclassification of products or repeal or modification of part or all of the Patient Protection and Affordable Care Act (the "ACA");
- risks inherent in doing business on an international level, including currency risks, regulatory requirements, political risks, export restrictions and other trade barriers;
- the disruption of production at our manufacturing facilities or facilities of third parties on which we rely and/or of our ability to supply product due to raw material shortages, labor shortages, physical damage to our or third parties' facilities, COVID-19 (including the impact of COVID-19 on suppliers of key raw materials), product testing, transportation delays or regulatory or other governmental actions, and the duration and impact of any such disruptions;
- our reliance on major customers and risks related to delays in payment of accounts receivable by major customers;
- risks from rising costs of raw materials and our ability to pass along increased costs to our customers;
- risks related to our growth strategy;
- our continued ability to attract and retain highly skilled and qualified personnel;
- the costs and other effects of litigation, governmental investigations, legal and administrative cases and proceedings, settlements and investigations;
- government contracting risks, including the appropriations process and funding priorities, potential bureaucratic delays in awarding contracts, process errors, politics or other pressures, and the risk that government tenders and contracts may be subject to cancellation, delay, restructuring or substantial delayed payments;
- a governmental tender award indicates acceptance of the bidder's price rather than an order or guarantee of the purchase of any minimum number of units, and as a result government ministries or other public health sector customers may order and purchase fewer units than the full maximum tender amount;
- our ability to identify, successfully negotiate and complete suitable acquisitions, out-licensing transactions, in-licensing transactions or other strategic initiatives and to realize any potential benefits of such transactions or initiatives; and
- our ability to successfully integrate acquired businesses, technologies or products.

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All forward-looking statements in this report should be considered in the context of the risks and other factors described above in Part II, Item 1A, "Risk Factors" below in this report, and in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended **September 30, 2021** **September 30, 2022**. The Company undertakes no obligation to make any revisions to the forward-looking statements contained in this report or to update them to reflect events or circumstances occurring after the date of this report except as required by applicable law.

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##### PART I. FINANCIAL INFORMATION

###### Item 1. Financial Statements

VERU INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30,	September 30,	December 31,	30,	September

	2022	2021	2022	2022
<b>Assets</b>				
Current assets:				
Cash and cash equivalents	\$ 100,550,610	\$ 122,359,535	\$ 46,927,187	\$ 80,190,675
Accounts receivable, net	8,302,745	8,794,224	3,864,310	3,550,895
Notes receivable	—	5,000,000		
Inventory, net	7,722,551	5,574,253		
Inventories, net			8,732,627	8,618,944
Prepaid research and development costs	9,611,066	9,174,586	10,416,934	10,444,587
Prepaid expenses and other current assets	2,173,722	850,889	3,067,587	1,964,373
Total current assets	128,360,694	151,753,487	73,008,645	104,769,474
Plant and equipment, net	1,081,710	592,603	1,425,970	1,185,766
Operating lease right-of-use assets	4,970,311	969,839	4,600,783	4,786,915
Deferred income taxes	13,005,533	13,024,550	13,052,163	12,965,985
Intangible assets, net	3,995,238	4,048,810	3,959,524	3,977,381
Goodwill	6,878,932	6,878,932	6,878,932	6,878,932
Other assets	2,284,890	878,502	856,435	1,561,564
Total assets	\$ 160,577,308	\$ 178,146,723	\$ 103,782,452	\$ 136,126,017
<b>Liabilities and Stockholders' Equity</b>				
Current liabilities:				
Accounts payable	\$ 6,936,312	\$ 3,409,771	\$ 10,566,962	\$ 22,003,394
Accrued research and development costs	10,721,360	2,020,445	12,678,176	9,071,503
Accrued compensation	4,016,771	4,986,058	7,135,943	5,986,557
Accrued expenses and other current liabilities	2,133,286	1,615,922	7,027,422	2,249,995
Residual royalty agreement liability, short-term portion	3,050,135	3,237,211	1,688,691	1,169,095
Operating lease liability, short-term portion	951,574	497,903	983,253	957,085
Total current liabilities	27,809,438	15,767,310	40,080,447	41,437,629
Residual royalty agreement liability, long-term portion	11,557,190	9,397,136	10,550,764	9,656,441
Operating lease liability, long-term portion	4,264,458	609,921	3,963,202	4,093,667
Deferred income taxes	63,426	63,426	63,426	81,067
Other liabilities	15,000	14,986	25,755	18,577
Total liabilities	43,709,512	25,852,779	54,683,594	55,287,381
Commitments and contingencies (Note 12)				
Stockholders' equity:				
Preferred stock; no shares issued and outstanding at June 30, 2022 and September 30, 2021	—	—	—	—
Common stock, par value \$0.01 per share; 154,000,000 shares authorized, 82,311,689 and 82,153,452 shares issued and 80,127,985 and 79,969,748 shares outstanding at June 30, 2022 and September 30, 2021, respectively	823,117	821,535		
Preferred stock; no shares issued and outstanding at December 31, 2022 and September 30, 2022				
Common stock, par value \$0.01 per share; 154,000,000 shares authorized, 82,806,832 and 82,692,598 shares issued and 80,623,128 and 80,508,894 shares outstanding at December 31, 2022 and September 30, 2022, respectively			828,068	826,926
Additional paid-in-capital	248,984,393	241,658,711	259,075,291	253,974,032
Accumulated other comprehensive loss	(581,519)	(581,519)	(581,519)	(581,519)
Accumulated deficit	(124,551,590)	(81,798,178)	(202,416,377)	(165,574,198)
Treasury stock, 2,183,704 shares, at cost	(7,806,605)	(7,806,605)	(7,806,605)	(7,806,605)
Total stockholders' equity	116,867,796	152,293,944	49,098,858	80,838,636
Total liabilities and stockholders' equity	\$ 160,577,308	\$ 178,146,723	\$ 103,782,452	\$ 136,126,017

See notes to unaudited condensed consolidated financial statements.

## VERU INC.

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	Three Months Ended		Nine Months Ended		Three Months Ended	
	June 30,		June 30,		December 31,	
	2022	2021	2022	2021	2022	2021
Net revenues	\$ 9,602,195	\$ 17,655,592	\$ 36,765,721	\$ 45,613,068	\$ 2,507,794	\$ 14,135,132
Cost of sales	2,533,572	3,782,480	6,679,738	9,995,023	1,805,739	2,293,050
Gross profit	7,068,623	13,873,112	30,085,983	35,618,045	702,055	11,842,082
Operating expenses:						
Research and development	18,133,412	11,188,246	43,755,677	24,438,813	18,744,349	10,081,161
Selling, general and administrative	10,758,986	5,556,730	24,881,330	14,745,507	17,545,865	6,723,206
Total operating expenses	28,892,398	16,744,976	68,637,007	39,184,320	36,290,214	16,804,367
Gain on sale of PREBOOST® business	—	—	—	18,410,158	—	—
Operating loss					(35,588,159)	(4,962,285)
Operating (loss) income	(21,823,775)	(2,871,864)	(38,551,024)	14,843,883		
Non-operating expenses:						
Non-operating income (expenses):						
Interest expense	(1,185,093)	(1,287,525)	(3,556,477)	(3,728,259)	(873,230)	(1,158,682)
Change in fair value of derivative liabilities	881,000	(1,372,000)	(557,000)	(2,029,000)	(670,000)	(209,000)
Other income (expense), net	69,895	(34,540)	135,897	(170,841)		
Other income, net					220,932	64,616
Total non-operating expenses	(234,198)	(2,694,065)	(3,977,580)	(5,928,100)	(1,322,298)	(1,303,066)
(Loss) income before income taxes	(22,057,973)	(5,565,929)	(42,528,604)	8,915,783		
Loss before income taxes					(36,910,457)	(6,265,351)
Income tax expense (benefit)	137,603	(2,873,063)	224,808	(2,773,071)		
Income tax (benefit) expense					(68,278)	114,655
Net (loss) income	\$ (22,195,576)	\$ (2,692,866)	\$ (42,753,412)	\$ 11,688,854		
Net loss					\$ (36,842,179)	\$ (6,380,006)
Net (loss) income per basic common share outstanding	\$ (0.28)	\$ (0.03)	\$ (0.53)	\$ 0.16		
Net loss per basic and diluted common shares outstanding					\$ (0.46)	\$ (0.08)
Basic weighted average common shares outstanding	80,088,431	79,729,370	80,054,594	75,054,871		
Net (loss) income per diluted common share outstanding	\$ (0.28)	\$ (0.03)	\$ (0.53)	\$ 0.14		
Diluted weighted average common shares outstanding	80,088,431	79,729,370	80,054,594	82,807,156		
Basic and diluted weighted average common shares outstanding					80,558,670	80,023,168

See notes to unaudited condensed financial statements.

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## VERU INC.

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

Accumulated			Accumulated		
Additional	Other	Treasury	Additional	Other	Treasury

	Common Stock		Paid-in Capital	Comprehensive Loss	Accumulated Deficit	Stock, at Cost	Total	Common Stock		Paid-in Capital	Comprehensive Loss	Accumulated Deficit	Stock, at Cost
	Shares	Amount						Shares	Amount				
Balance at September 30, 2022								82,692,598	\$826,926	\$253,974,032	\$ (581,519)	\$ (165,574,198)	\$ (7,806,605)
Share-based compensation								—	—	4,845,269	—	—	—
Issuance of shares pursuant to share-based awards								114,234	1,142	255,990	—	—	—
Net loss								—	—	—	—	—	(36,842,179)
Balance at December 31, 2022								82,806,832	\$828,068	\$259,075,291	\$ (581,519)	\$ (202,416,377)	\$ (7,806,605)
Balance at September 30, 2021	82,153,452	\$821,535	\$241,658,711	\$ (581,519)	\$ (81,798,178)	\$ (7,806,605)	\$152,293,944	82,153,452	\$821,535	\$241,658,711	\$ (581,519)	\$ (81,798,178)	\$ (7,806,605)
Share-based compensation	—	—	1,880,428	—	—	—	1,880,428	—	—	1,880,428	—	—	—
Issuance of shares pursuant to share-based awards	79,334	793	209,076	—	—	—	209,869	79,334	793	209,076	—	—	—
Net loss	—	—	—	—	(6,380,006)	—	(6,380,006)	—	—	—	—	—	(6,380,006)
Balance at December 31, 2021	82,232,786	822,328	243,748,215	\$ (581,519)	\$ (88,178,184)	\$ (7,806,605)	148,004,235	82,232,786	\$822,328	\$243,748,215	\$ (581,519)	\$ (88,178,184)	\$ (7,806,605)
Share-based compensation	—	—	2,124,941	—	—	—	2,124,941	—	—	—	—	—	—
Issuance of shares pursuant to share-based awards	17,267	173	46,924	—	—	—	47,097	—	—	—	—	—	—
Net loss	—	—	—	—	(14,177,830)	—	(14,177,830)	—	—	—	—	—	(14,177,830)
Balance at March 31, 2022	82,250,053	822,501	245,920,080	\$ (581,519)	\$ (102,356,014)	\$ (7,806,605)	135,998,443	—	—	—	—	—	—
Share-based compensation	—	—	2,910,976	—	—	—	2,910,976	—	—	—	—	—	—
Issuance of shares pursuant to share-based awards	61,636	616	153,337	—	—	—	153,953	—	—	—	—	—	—
Net loss	—	—	—	—	(22,195,576)	—	(22,195,576)	—	—	—	—	—	(22,195,576)
Balance at June 30, 2022	82,311,689	\$823,117	\$248,984,393	\$ (581,519)	\$ (124,551,590)	\$ (7,806,605)	\$116,867,796	—	—	—	—	—	—

See notes to unaudited condensed consolidated financial statements.

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## VERU INC.

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (CONTINUED)

	Accumulated							Treasury Stock, at Cost	Total		
	Common Stock		Additional Paid-in Capital	Other Comprehensive Loss	Accumulated Deficit	Treasury					
	Shares	Amount				Stock	at Cost				
Balance at September 30, 2020	72,047,385	\$ 720,474	\$ 126,971,518	\$ (581,519)	\$ (89,192,552)	\$ (7,806,605)	\$ 30,111,316				
Share-based compensation	—	—	785,297	—	—	—	—	785,297			
Issuance of shares pursuant to share-based awards	468,611	4,686	619,133	—	—	—	—	—	623,819		
Issuance of shares pursuant to common stock											
purchase warrants	1,574,611	15,746	(15,746)	—	—	—	—	—	—		
Net income	—	—	—	—	17,227,701	—	—	17,227,701			
Balance at December 31, 2020	74,090,607	740,906	128,360,202	(581,519)	(71,964,851)	(7,806,605)	48,748,133				
Share-based compensation	—	—	1,002,281	—	—	—	—	1,002,281			
Issuance of shares pursuant to share-based awards	357,297	3,573	645,702	—	—	—	—	649,275			
Shares issued in connection with public offering of common stock, net of fees and costs	7,419,354	74,194	107,868,104	—	—	—	—	107,942,298			
Net loss	—	—	—	—	(2,845,981)	—	—	(2,845,981)			
Balance at March 31, 2021	81,867,258	818,673	237,876,289	(581,519)	(74,810,832)	(7,806,605)	155,496,006				
Share-based compensation	—	—	1,900,085	—	—	—	—	1,900,085			
Issuance of shares pursuant to share-based awards	170,194	1,702	263,351	—	—	—	—	265,053			
Net loss	—	—	—	—	(2,692,866)	—	—	(2,692,866)			
Balance at June 30, 2021	82,037,452	\$ 820,375	\$ 240,039,725	\$ (581,519)	\$ (77,503,698)	\$ (7,806,605)	\$ 154,968,278				

See notes to unaudited condensed financial statements.

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## VERU INC.

## UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

OPERATING ACTIVITIES	Nine Months Ended		Three Months Ended	
	June 30,		December 31,	
	2022	2021	2022	2021
Net (loss) income	\$ (42,753,412)	\$ 11,688,854		
Adjustments to reconcile net (loss) income to net cash used in operating activities:				
Net loss				\$ (36,842,179) \$ (6,380,006)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	147,156	170,713	63,218	43,228
Noncash change in right-of-use assets	411,002	282,843	186,132	100,822
Noncash interest expense, net of interest paid	1,415,978	(2,923,628)	743,919	376,358
Share-based compensation	6,916,345	3,687,663	4,845,269	1,880,428
Gain on sale of PREBOOST® business	—	(18,410,158)		
Deferred income taxes	19,017	(2,912,778)	(103,819)	93,421
Change in fair value of derivative liabilities	557,000	2,029,000	670,000	209,000
Other	63,133	172,085	2,921	(52,776)
Changes in current assets and liabilities:				
Increase in accounts receivable	(930,021)	(3,083,306)		
Increase in inventory	(2,216,377)	(416,867)		

Decrease in accounts receivable		400,585	724,683
(Increase) decrease in inventories		(116,604)	725,161
Increase in prepaid expenses and other assets	(1,737,701)	(9,610,334)	(1,084,432)
Increase in accounts payable	3,526,541	2,115,007	
Increase in accrued expenses and other current liabilities	8,258,099	2,783,696	
(Decrease) increase in accounts payable		(11,436,432)	677,937
Increase (decrease) in accrued expenses and other current liabilities		8,241,691	(2,831,116)
Decrease in operating lease liabilities	(303,266)	(337,346)	(104,297)
Net cash used in operating activities	(26,626,506)	(14,764,556)	(34,534,028)
<b>INVESTING ACTIVITIES</b>			
Cash proceeds from sale of PREBOOST® business	5,000,000	15,000,000	—
Capital expenditures	(584,245)	(154,416)	(285,565)
Net cash provided by investing activities	4,415,755	14,845,584	
Net cash (used in) provided by investing activities			(285,565) 2,197,791
<b>FINANCING ACTIVITIES</b>			
Proceeds from stock option exercises	410,919	1,538,147	257,132
Proceeds from sale of shares in public offering, net of fees	—	108,099,988	
Payment of costs related to public offering	—	(137,690)	
Proceeds from premium finance agreement	—	1,061,442	1,425,174
Installment payments on premium finance agreement	—	(1,061,442)	(126,201)
Cash paid for debt portion of finance lease	(9,093)	(14,283)	—
Net cash provided by financing activities	401,826	109,486,162	1,556,105
Net (decrease) increase in cash	(21,808,925)	109,567,190	
Net decrease in cash			(33,263,488) (6,255,574)
<b>CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD</b>	122,359,535	13,588,778	80,190,675
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 100,550,610</b>	<b>\$ 123,155,968</b>	<b>\$ 46,927,187</b>
Supplemental disclosure of cash flow information:			\$ 116,103,961
Cash paid for interest	\$ 2,140,499	\$ 6,651,887	\$ 129,311
Schedule of non-cash investing and financing activities:			\$ 782,324
Right-of-use asset recorded in exchange for lease liabilities	\$ 4,411,474	\$ —	
Notes receivable for sale of PREBOOST® business	\$ —	\$ 5,000,000	
Costs related to public offering in accounts payable or accrued expenses and other current liabilities	\$ —	\$ 20,000	

See notes to unaudited condensed consolidated financial statements.

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### VERU INC.

### NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

#### Note 1 – Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements for Veru Inc. ("we," "our," "us," "Veru" or the "Company") have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for reporting of interim financial information. Pursuant to these rules and regulations, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP) have been condensed or omitted, although the Company believes that the disclosures made are adequate to make the information not misleading. Accordingly, these statements do not include all the disclosures normally required by U.S. GAAP for annual financial statements and should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations contained in this report and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the fiscal year ended **September 30, 2021** **September 30, 2022**. The accompanying condensed consolidated balance sheet as of **September 30, 2021** **September 30, 2022** has been derived from our audited financial statements. The unaudited condensed consolidated statements of operations and cash flows for the three and nine months ended **June 30, 2022** **December 31, 2022** are not necessarily indicative of the results to be expected for any future period or for the fiscal year ending **September 30, 2022** **September 30, 2023**.

The preparation of our unaudited interim condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from those estimates.

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements contain all adjustments (consisting of only normally recurring adjustments) necessary to present fairly the financial position and results of operations as of the dates and for the periods presented.

**Principles of consolidation and nature of operations:** Veru Inc. is referred to in these notes collectively with its subsidiaries as "we," "our," "us," "Veru" or the "Company." The consolidated financial statements include the accounts of Veru and its wholly owned subsidiaries, Veru International Holdco Inc., Aspen Park Pharmaceuticals, Inc. (APP), Veru International Holdco Inc., and The Female Health Company Limited, and Limited; The Female Health Company Limited's wholly owned subsidiary, The Female Health Company (UK) plc (The Female Health Company Limited and The Female Health Company (UK) plc, collectively, the "U.K. subsidiary"), and; The Female Health Company (UK) plc's wholly owned subsidiary, The Female Health Company (M) SDN.BHD (the "Malaysia subsidiary"); and Veru International Holdco Inc.'s wholly owned subsidiaries, Veru Biopharma UK Limited, Veru Biopharma Europe Limited, and Veru Biopharma Netherlands B.V. All significant intercompany transactions and accounts have been eliminated in consolidation. The Company is a biopharmaceutical company focused on developing novel medicines for COVID-19 and other viral and acute respiratory distress syndrome (ARDS)-related diseases and for the management of breast and prostate cancers. The Company has multiple drug products under clinical development. The Company also has two approved products: ENTADFI™, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021, and the FC2 Female Condom/FC2 Internal Condom® (FC2), an FDA-approved product for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections. All infections, and ENTADFI™ (finasteride and tadalafil) capsules for oral use, a new treatment for benign prostatic hyperplasia that was approved by the FDA in December 2021. Most of the Company's net revenues during the three and nine months ended June 30, 2022 December 31, 2022 and the three months ended June 30, 2021 and most of the Company's net revenues during the nine months ended June 30, 2021 2021 were derived from sales of FC2.

**Segments:** We regularly review our operating segments and the approach used by management to evaluate performance and allocate resources. Prior to the commercialization of ENTADFI, we managed two distinct business segments: Pharmaceuticals, which engaged exclusively in research and development activities and FC2, which included the Company's single commercial product. Beginning in the second quarter of 2022, as a result of added commercialization efforts related to ENTADFI, the Company now operates as a single operating segment. Our determination that we operate as a single segment is consistent with the financial information regularly reviewed by the chief operating decision maker (CODM) for purposes of evaluating performance, allocating resources, setting incentive compensation targets, and planning and forecasting for future periods. Our CODM allocates resources and assesses financial performance on a consolidated basis.

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**Other comprehensive (loss) income loss:** Accounting principles generally require that recognized revenue, expenses, gains and losses be included in net (loss) income loss. Although certain changes in assets and liabilities, such as foreign currency translation adjustments, are reported as a separate component of the equity section of the accompanying unaudited condensed consolidated balance sheets, these items, along with net (loss) income, loss, are components of other comprehensive loss. For the three and nine months ended June 30, 2022 December 31, 2022 and 2021, comprehensive (loss) income loss is equivalent to the reported net (loss) income, loss.

**Recently adopted Recent accounting pronouncements not yet adopted:** In December 2019, the FASB We have reviewed all recently issued ASU 2019-12, Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes. The new guidance eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period, accounting pronouncements and the recognition of deferred tax liabilities for outside basis differences. It also clarifies and simplifies other aspects of the accounting for income taxes. The Company adopted ASU 2019-12 have determined that such standards that are not yet effective will not have a material impact on a prospective basis effective October 1, 2021. The adoption of ASU 2019-12 did not impact our consolidated financial statements and related disclosures, or do not otherwise apply to our operations.

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### Note 2 – Sale of PREBOOST® Business Liquidity

On December 8, 2020, The Company anticipates that we will continue to consume cash and incur losses as we develop and commercialize our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, the Company entered into an Asset Purchase Agreement, pursuant to which estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of our drug candidates and obtain regulatory approvals. The Company's future capital requirements will depend on many factors.

The Company believes its current cash position, cash expected to be generated from sales of FC2, and its ability to secure equity financing or other financing alternatives will be adequate to fund planned operations of the Company sold substantially all of the assets related to the Company's PREBOOST® business. PREBOOST® is a 4% benzocaine medicated individual wipe for the treatment of premature ejaculation. The transaction closed next 12 months. To the extent the Company may need additional capital for its operations or the conditions for raising capital are favorable, the Company may access financing alternatives that may include debt financing, common stock offerings, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's current effective shelf registration statement on December 8, 2020. The purchase price for the transaction was \$20.0 million, consisting of \$15.0 million paid at closing, Form S-3 (File No. 333-239493) or under a \$2.5 million note receivable due 12 months after closing and a \$2.5 million note receivable due 18 months after closing, new registration statement. The Company collected the \$5.0 million due on the notes receivable during the nine months ended June 30, 2022. Total assets sold, consisting of intangible assets, had a net book value of approximately \$1.6 million, resulting in a pre-tax gain on sale of approximately \$18.4 million. The Company had income before income taxes of \$327,000 during the nine months ended June 30, 2021 related intends to the PREBOOST®

business before the sale, be opportunistic when pursuing equity or debt financing, which could include selling common stock under its common stock purchase agreement with Aspire Capital Fund, LLC (see Note 9).

### Note 3 – Fair Value Measurements

FASB Accounting Standards Codification (ASC) Topic 820 specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement). The three levels of the fair value hierarchy are as follows:

Level 1 – Quoted prices for identical instruments in active markets.

Level 2 – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 – Instruments with primarily unobservable value drivers.

As of June 30, 2022 December 31, 2022 and September 30, 2021 September 30, 2022, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, were classified within Level 3 of the fair value hierarchy.

The following table provides a reconciliation of the beginning and ending liability balance associated with embedded derivatives measured at fair value using significant unobservable inputs (Level 3) as of June 30, 2022 December 31, 2022 and 2021:

	Nine Months Ended June 30,		Three Months Ended December 31,	
	2022		2021	
	2022	2021	2022	2021
Beginning balance	\$ 7,851,000	\$ 4,182,000	\$ 4,294,000	\$ 7,851,000
Change in fair value of derivative liabilities	557,000	2,029,000	670,000	209,000
Ending balance	\$ 8,408,000	\$ 6,211,000	\$ 4,964,000	\$ 8,060,000

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The expense associated with the change in fair value of the embedded derivatives is included as a separate line item on the accompanying unaudited condensed consolidated statements of operations.

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The liabilities associated with embedded derivatives represent the fair value of the change of control provisions provision in the Credit Agreement and Residual Royalty Agreement. See Note 8 for additional information. There is no current observable market for these types of derivatives. The Company previously determined the fair value of the embedded derivatives using a Monte Carlo simulation model. Since the Credit Agreement has been satisfied as of September 30, 2021, estimates the fair value of the embedded derivative within the Residual Royalty Agreement has been calculated by using a scenario-based method, whereby different scenarios are valued and probability weighted. The Company determined that with only the embedded derivative under the Residual Royalty Agreement remaining, there is no material difference between these two valuation models. The scenario-based valuation model incorporates transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. A significant increase in projected FC2 revenues or a significant increase in the probability or acceleration of the timing of a change of control event, in isolation, would result in a significantly higher fair value measurement of the liability associated with the embedded derivative.

The following tables present quantitative information about the inputs and valuation methodologies used to determine the fair value of the embedded derivatives classified in Level 3 of the fair value hierarchy as of June 30, 2022 December 31, 2022 and September 30, 2021 September 30, 2022:

Valuation Methodology	Significant Unobservable Input	June December 31, 2022	September 30, 2022
Scenario-Based	Estimated change of control dates	September 2023 to September 2025	September 2023 to September 2025
	Discount rate	11.6% 10.2% to 11.9% 10.7%	13.6% to 14.2%
	Probability of change of control	20% to 90%	
Valuation Methodology	Significant Unobservable Input	September 30, 2021	
Monte Carlo Simulation	Estimated change of control dates	September 2022 to September 2025	
	Discount rate	6.6% to 7.9%	
	Probability of change of control	20% to 90%	

### Note 4 – Revenue from Contracts with Customers

The Company generates nearly all its revenue from direct product sales. Revenue from direct product sales is generally recognized when the customer obtains control of the product, which occurs at a point in time, and may be upon shipment or upon delivery based on the contractual shipping terms of a contract. Sales taxes and other similar taxes that the Company collects concurrent with revenue-producing activities are excluded from revenue.

The amount of consideration the Company ultimately receives varies depending upon sales discounts, and other incentives that the Company may offer, which are accounted for as variable consideration when estimating the amount of revenue to recognize. The estimate of variable consideration requires significant judgment. The Company includes estimated amounts in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. The estimates of variable consideration and determination of whether to include estimated amounts in the transaction price are based largely upon an assessment of current contract sales terms and historical payment experience.

Product returns are typically not significant because returns are generally not allowed unless the product is damaged at time of receipt.

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The Company's revenue is from sales of FC2 in the U.S. prescription channel and direct sales of FC2 in the global public health sector, and also included sales of PREBOOST® medicated wipes for prevention of premature ejaculation before ENTADFI, which is currently being distributed in the sale of the PREBOOST® business, U.S. through pharmaceutical distribution channels. The following table presents net revenues from these three categories:

	Three Months Ended		Nine Months Ended		Three Months Ended	
	June 30,		June 30,		December 31,	
	2022	2021	2022	2021	2022	2021
FC2						
U.S. prescription channel	\$ 6,736,158	\$ 13,501,862	\$ 29,900,890	\$ 32,916,343	\$ 163,004	\$ 11,574,266
Global public health sector	2,866,037	4,153,730	6,864,831	11,833,894	2,336,997	2,560,866
Total FC2	9,602,195	17,655,592	36,765,721	44,750,237	2,500,001	14,135,132
PREBOOST®	—	—	—	862,831	—	—
ENTADFI					7,793	—
Net revenues	\$ 9,602,195	\$ 17,655,592	\$ 36,765,721	\$ 45,613,068	\$ 2,507,794	\$ 14,135,132

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The following table presents net revenue by geographic area:

	Three Months Ended		Nine Months Ended		Three Months Ended	
	June 30,		June 30,		December 31,	
	2022	2021	2022	2021	2022	2021
United States	\$ 7,024,786	\$ 14,080,810	\$ 30,780,271	\$ 35,049,646	\$ 809,377	\$ 11,908,525
Uganda					257,469	*
Other	2,577,409	3,574,782	5,985,450	10,563,422	1,440,948	2,226,607
Net revenues	\$ 9,602,195	\$ 17,655,592	\$ 36,765,721	\$ 45,613,068	\$ 2,507,794	\$ 14,135,132

\*Less than 10% of total net revenues

The Company's performance obligations consist mainly of transferring control of products identified in the contracts which occurs either when: i) the product is made available to the customer for shipment; ii) the product is shipped via common carrier; or iii) the product is delivered to the customer or distributor, in accordance with the terms of the agreement. Some of the Company's contracts require the customer to make advanced payments prior to transferring control of the products. These advanced payments create a contract liability for the Company. The balances of the Company's contract liability, included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balance sheets, were approximately \$312,000 \$813,000 and \$132,000 \$342,000 at June 30, 2022 December 31, 2022 and September 30, 2021 September 30, 2022, respectively.

#### Note 5 – Accounts Receivable and Concentration of Credit Risk

The Company's standard credit terms vary from 30 to 120 days, depending on the class of trade and customary terms within a territory, so accounts receivable are affected by the mix of purchasers within the period. As is typical in the Company's business, extended credit terms may occasionally be offered as a sales promotion or for certain sales. For sales to the Company's distributor in Brazil, the Company has agreed to credit terms of up to 90 days subsequent to clearance of the product by the Ministry of Health in Brazil. The Company classified approximately \$1.4 \$0.7 million of trade receivables with its distributor in Brazil as long-term as of June 30, 2022 September 30, 2022, because payment was expected in greater than one year. The long-term portion of trade receivables is included in other assets on the accompanying unaudited condensed consolidated balance sheet.

The components of accounts receivable consisted of the following at June 30, 2022 December 31, 2022 and September 30, 2021 September 30, 2022:

June 30,	September 30,	December 31,	September 30,

	2022	2021	2022	2022
Trade receivables, gross	\$ 9,756,866	\$ 8,938,849	\$ 3,888,248	\$ 4,289,892
Less: allowance for doubtful accounts	(14,143)	(20,643)	(12,143)	(12,143)
Less: allowance for sales returns and payment term discounts	(11,978)	(123,982)	(11,795)	(12,854)
Less: long-term trade receivables*	(1,428,000)	—	—	(714,000)
Accounts receivable, net	\$ 8,302,745	\$ 8,794,224	\$ 3,864,310	\$ 3,550,895

\*Included in other assets on the accompanying unaudited condensed consolidated balance sheets

At **June 30, 2022** **December 31, 2022** and at **September 30, 2021** **September 30, 2022**, no customers had a current accounts receivable balance that represented greater than 10% of current assets.

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At **June 30, 2022** **December 31, 2022**, two customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 76% of net accounts receivable and long-term trade receivables in the aggregate. At **September 30, 2022**, two customers had an accounts receivable balance greater than 10% of net accounts receivable and long-term trade receivables, representing 88% 83% of net accounts receivable and long-term trade receivables in the aggregate. At **September 30, 2021**, three customers had an accounts receivable balance greater than 10% of net accounts receivable, representing 90% of net accounts receivable in the aggregate.

For the three months ended **June 30, 2022** **December 31, 2022**, there were three customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 92% 64% of the Company's net revenues in the aggregate. For the three months ended **June 30, 2021** **December 31, 2021**, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 75% 80% of the Company's net revenues in the aggregate.

For the nine months ended **June 30, 2022**, there were two customers whose individual net revenue to the Company exceeded 10% 13

[Table of the Company's net revenues, representing 78% of the Company's net revenues in the aggregate. For the nine months ended June 30, 2021, there were two customers whose individual net revenue to the Company exceeded 10% of the Company's net revenues, representing 71% of the Company's net revenues in the aggregate.](#) [Contents](#)

The Company maintains an allowance for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments on accounts receivable. Management determines the allowance for doubtful accounts by identifying troubled accounts and by using historical experience applied to an aging of accounts. Management also periodically evaluates individual customer receivables and considers a customer's financial condition, credit history, and the current economic conditions. Accounts receivable are charged-off when deemed uncollectible. There was no material change in the allowance for doubtful accounts for the **nine** **three** months ended **June 30, 2022** **December 31, 2022** and 2021.

Recoveries of accounts receivable previously charged off are recorded when received. In the global public health sector, the Company's customers are primarily large global agencies, non-government organizations, ministries of health and other governmental agencies, which purchase and distribute FC2 for use in HIV/AIDS prevention and family planning programs. In the U.S., the Company's customers include telemedicine providers who sell into the prescription channel.

#### Note 6 – Balance Sheet Information

##### Inventory Inventories

Inventories are valued at the lower of cost or net realizable value. The cost is determined using the first-in, first-out (FIFO) method. Inventories are also written down for management's estimates of product which will not sell prior to its expiration date. Write-downs of inventories establish a new cost basis which is not increased for future increases in the net realizable value of inventories or changes in estimated obsolescence.

[Inventory Inventories](#) consisted of the following at **June 30, 2022** **December 31, 2022** and **September 30, 2021** **September 30, 2022**:

	June 30, 2022	September 30, 2021	December 31, 2022	September 30, 2022
<b>FC2:</b>				
Raw material	\$ 1,599,984	\$ 1,371,133	\$ 1,686,725	\$ 1,662,712
Work in process	54,004	112,915	766,538	872,596
Finished goods	5,162,190	4,547,690	6,296,420	6,099,343
<b>FC2, gross</b>	<b>6,816,178</b>	<b>6,031,738</b>		
<b>Inventories, gross</b>			<b>8,749,683</b>	<b>8,634,651</b>
Less: inventory reserves	(83,424)	(457,485)	(17,056)	(15,707)
<b>FC2, net</b>	<b>6,732,754</b>		<b>5,574,253</b>	
<b>ENTADFI:</b>				
Raw material	141,079	—	—	—
Work in process	848,718	—	—	—

Total ENTADFI	989,797	—
Inventory, net	\$ 7,722,551	\$ 5,574,253
Inventories, net		\$8,732,627 \$ 8,618,944

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### Fixed Assets

We record equipment, furniture and fixtures, and leasehold improvements at historical cost. Expenditures for maintenance and repairs are recorded to expense. Depreciation and amortization are primarily computed using the straight-line method. Depreciation and amortization are computed over the estimated useful lives of the respective assets. Leasehold improvements are depreciated on a straight-line basis over the lesser of the remaining lease term or the estimated useful lives of the improvements.

Plant and equipment consisted of the following at **June 30, 2022** **December 31, 2022** and **September 30, 2021** **September 30, 2022**:

	Estimated Useful Life	June 30,		September 30,		December September		
		2022		2021		Estimated Useful Life	31,	30,
		2022	2021	2021	2020	2022	2022	2022
<b>Plant and equipment:</b>								
Manufacturing equipment	5 - 8 years	\$ 2,902,718	\$ 2,875,744	5 - 8 years	\$ 3,153,918	\$ 2,902,715		
Office equipment, furniture and fixtures	3 - 10 years	1,303,730	991,146	3 - 10 years	1,474,837	1,440,475		
Leasehold improvements	3 - 8 years	484,460	298,886	3 - 8 years	484,460	484,460		
Total plant and equipment		4,690,908	4,165,776			5,113,215	4,827,650	
Less: accumulated depreciation and amortization		(3,609,198)	(3,573,173)			(3,687,245)	(3,641,884)	
Plant and equipment, net		\$ 1,081,710	\$ 592,603			\$ 1,425,970	\$ 1,185,766	

Depreciation expense was approximately \$39,000 \$45,000 and \$21,000 \$25,000 for the three months ended June 30, 2022 and 2021, respectively, and approximately \$94,000 and \$75,000 for the nine months ended June 30, 2022 December 31, 2022 and 2021, respectively. Plant and equipment included \$171,000 \$561,000 and \$210,000 \$276,000 at June 30, 2022 December 31, 2022 and September 30, 2021 September 30, 2022, respectively, for deposits on equipment, furniture, and leasehold improvements, which have not been placed into service; therefore, the Company has not started to record depreciation expense.

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### Note 7 – Intangible Assets and Goodwill

#### Intangible Assets

The gross carrying amounts and net book value of intangible assets were as follows at **June 30, 2022** **December 31, 2022**:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount			Accumulated Amortization			Net Book Value		
				2022	2021	2020	2022	2021	2020	2022	2021	2020
<b>Intangible asset with finite life:</b>												
Covenants not-to-compete	\$ 500,000	\$ 404,762	\$ 95,238	\$ 500,000	\$ 440,476	\$ 59,524						
<b>Indefinite-lived intangible assets:</b>												
Acquired in-process research and development assets	3,900,000	—	3,900,000	3,900,000	3,900,000	—	3,900,000	3,900,000	3,900,000	—	3,900,000	3,900,000
Total intangible assets	\$ 4,400,000	\$ 404,762	\$ 3,995,238	\$ 4,400,000	\$ 440,476	\$ 3,959,524						

The gross carrying amounts and net book value of intangible assets were as follows at **September 30, 2021** **September 30, 2022**:

	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount			Accumulated Amortization			Net Book Value		
				2022	2021	2020	2022	2021	2020	2022	2021	2020
<b>Intangible asset with finite life:</b>												
Covenants not-to-compete	\$ 500,000	\$ 351,190	\$ 148,810	\$ 500,000	\$ 422,619	\$ 77,381						
<b>Indefinite-lived intangible assets:</b>												
Acquired in-process research and development assets	3,900,000	—	3,900,000	3,900,000	3,900,000	—	3,900,000	3,900,000	3,900,000	—	3,900,000	3,900,000
Total intangible assets	\$ 4,400,000	\$ 351,190	\$ 4,048,810	\$ 4,400,000	\$ 422,619	\$ 3,977,381						

Amortization expense was approximately \$18,000 for the three months ended June 30, 2022 December 31, 2022 and 2021 and approximately \$54,000 and \$96,000 for the nine months ended June 30, 2022 and 2021, respectively.

## Goodwill

The carrying amount of goodwill at **June 30, 2022** **December 31, 2022** and **September 30, 2021** **September 30, 2022** was \$6.9 million. There was no change in the balance during the **nine** **three** months ended **June 30, 2022** **December 31, 2022** and **2021**. The Company's goodwill is assigned to the Research and Development reporting unit, which had a negative carrying amount as of December 31, 2022.

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### **Note 8 – Debt**

#### SWK Credit Agreement and Residual Royalty Agreements

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of \$10.0 million, which was advanced to the Company on the date of the Credit Agreement. After payment by the Company of certain fees and expenses of the Agent and the Lenders as required in the Credit Agreement, the Company received net proceeds of approximately \$9.9 million from the \$10.0 million loan under the Credit Agreement.

The Lenders were entitled to receive quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 as provided in the Credit Agreement until the Company paid 176.5% of the aggregate amount advanced to the Company under the Credit Agreement. The Company repaid the loan and return premium specified in the Credit Agreement in August 2021, and as a result has no further obligations under the Credit Agreement. The Agent has released its security interest in Company collateral previously pledged to secure its obligations under the Credit Agreement.

In connection with the Credit Agreement, the Company and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2, which commenced after the Company paid 175% of the aggregate amount advanced to the Company under the Credit Agreement based on a calculation of revenue-based payments under the Credit Agreement. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Residual Royalty Agreement, or (ii) mutual agreement of the parties. If a change of control or sale of the FC2 business occurs, the Agent will receive a payment that is the greater of (A) \$2.0 million or (B) the product of (x) 5% of the product revenue from net sales of FC2 for the most recently completed 12-month period multiplied by (y) five.

For accounting purposes, the \$10.0 million advance under the Credit Agreement was allocated between the Credit Agreement and the Residual Royalty Agreement on a relative fair value basis. A portion of the amount allocated to the Credit Agreement and a portion of the amount allocated to the Residual Royalty Agreement, in both cases equal to the fair value of the respective change of control provisions, was allocated to the an embedded derivative liabilities. liability. The derivative liabilities are liability is adjusted to fair market value at each reporting period.

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For financial statement presentation, the embedded derivative liabilities have liability has been included together with their respective its host instruments instrument as noted in the following tables. The debt discounts were amortized to interest expense over the term of the Credit Agreement using the effective interest method. Additionally, the Company recorded deferred loan issuance costs of approximately \$267,000 for legal fees incurred in connection with the Credit Agreement. The deferred loan issuance costs were presented as a reduction of the Credit Agreement obligation and were amortized to interest expense over the term of the Credit Agreement using the effective interest method, table.

At **June 30, 2022** **December 31, 2022** and **September 30, 2021** **September 30, 2022**, the Residual Royalty Agreement liability consisted of the following:

	<b>June 30, 2022</b>	<b>September 30, 2021</b>	<b>31, 2022</b>	<b>30, 2022</b>
Residual royalty agreement liability, fair value at inception	\$ 346,000	\$ 346,000	\$ 346,000	\$ 346,000
Add: accretion of liability using effective interest rate	9,138,587	5,582,110	10,824,138	9,950,908
Less: cumulative payments	(3,285,262)	(1,144,763)	(3,894,683)	(3,765,372)
Residual royalty agreement liability, excluding embedded derivative liability	6,199,325	4,783,347	7,275,455	6,531,536
Add: embedded derivative liability at fair value (see Note 3)	8,408,000	7,851,000	4,964,000	4,294,000
Total residual royalty agreement liability	14,607,325	12,634,347	12,239,455	10,825,536
Residual royalty agreement liability, short-term portion	(3,050,135)	(3,237,211)	(1,688,691)	(1,169,095)
Residual royalty agreement liability, long-term portion	\$ 11,557,190	\$ 9,397,136	\$ 10,550,764	\$ 9,656,441

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As the Company has repaid the original principal of \$10.0 million advanced in connection with the Credit Agreement and the Residual Royalty Agreement, payments under the Residual Royalty Agreement are classified as interest payments and included in operating activities on the accompanying unaudited condensed consolidated statements of cash flows. The short-term portion of the Residual Royalty Agreement liability represents the aggregate of the estimated quarterly payments on the Residual Royalty Agreement payable during the 12-month period subsequent to the balance sheet date.

Interest expense related on the accompanying unaudited condensed consolidated statements of operations relates to the Credit Agreement and the Residual Royalty Agreement consisted of amortization of the discounts, accretion of the liability for the Residual Royalty Agreement and amortization of the deferred issuance costs. For the three and nine months ended June 30, 2022 and 2021, interest expense related to the Credit Agreement and Residual Royalty Agreement was as follows: Agreement.

	Three Months Ended		Nine Months Ended	
	June 30, 2022	2021	June 30, 2022	2021
Amortization of discounts	\$ —	\$ 327,550	\$ —	\$ 1,400,039
Accretion of residual royalty agreement	1,185,093	952,276	3,556,477	2,295,313
Amortization of deferred issuance costs	—	7,699	—	32,907
Interest expense	\$ 1,185,093	\$ 1,287,525	\$ 3,556,477	\$ 3,728,259

#### Premium Finance Agreement

On November 1, 2020 November 1, 2022, the Company entered into a Premium Finance Agreement to finance \$1.1 \$1.4 million of its directors and officers liability insurance premium at an annual percentage rate of 3.94% 6.3%. The financing was payable in three quarterly eleven monthly installments of principal and interest, beginning on January 1, 2021 December 1, 2022. The last payment was made in June 2021 and there was no balance outstanding of the insurance premium liability is \$1.3 million as of June 30, 2022 or September 30, 2021. December 31, 2022 and is included in accrued expenses and other current liabilities on the accompanying unaudited condensed consolidated balance sheet.

#### Note 9 – Stockholders' Equity

##### Preferred Stock

The Company has 5,000,000 authorized shares designated as Class A Preferred Stock with a par value of \$0.01 per share. There are 1,040,000 shares of Class A Preferred Stock – Series 1 authorized; 1,500,000 shares of Class A Preferred Stock – Series 2 authorized; 700,000 shares of Class A Preferred Stock – Series 3 authorized; and 548,000 shares of Class A Preferred Stock – Series 4 (the "Series 4 Preferred Stock") authorized. There were no shares of Class A Preferred Stock of any series issued and outstanding at June 30, 2022 December 31, 2022 and September 30, 2021 September 30, 2022. The Company has 15,000 authorized shares designated as Class B Preferred Stock with a par value of \$0.50 per share. There were no shares of Class B Preferred Stock issued and outstanding at June 30, 2022 December 31, 2022 and September 30, 2021 September 30, 2022, and there was no activity during the nine three months then ended.

##### Common Stock Offering

On February 22, 2021, we completed an underwritten public offering of 7,419,354 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of \$15.50 per share. Net proceeds to the Company from this offering were approximately \$108.0 million after deducting underwriting discounts ended December 31, 2022 and commissions and costs paid by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-239493), 2021.

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##### Common Stock Purchase Warrants

In connection with the closing of the acquisition of APP (the "APP Acquisition") on October 31, 2016, the Company issued warrants to purchase up to 2,585,379 shares of the Company's common stock to Torreya Capital, the Company's then financial advisor (the "Financial Advisor Warrants"). The Financial Advisor Warrants had a five-year term expiring October 31, 2021, a cashless exercise feature and a strike price equal to \$1.93 per share. The Financial Advisor Warrants vested upon issuance. During the nine months ended June 30, 2021, the remaining outstanding Financial Advisor Warrants to purchase 2,326,841 shares of the Company's common stock were exercised using the cashless exercise feature, resulting in the issuance of 1,574,611 shares of common stock. As of June 30, 2022, there were no outstanding common stock purchase warrants.

##### Aspire Capital Purchase Agreement

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to \$23.9 million of the Company's common stock in the aggregate. Concurrently with entering into the 2020 Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to prepare and file under the Securities Act of 1933 one or more prospectus supplement for the sale or potential sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the 2020 Purchase Agreement.

Under the 2020 Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 200,000 shares of the Company's common stock per business day at a per share price (the "Purchase Price") equal to the lesser of the lowest sale price of the Company's common stock on the purchase date or the average of the three lowest closing sale prices for the Company's common stock during the ten consecutive trading days ending on the trading day immediately preceding the purchase date.

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount equal to 200,000 shares and the closing sale price of our common stock is equal to or greater than \$0.50 per share, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of common stock equal to up to 30% of the aggregate shares of the common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.

Since inception of the 2020 Purchase Agreement, we have sold 1,644,737 shares of common stock to Aspire Capital resulting in proceeds to the Company of \$5.0 million. The Company has not sold shares to Aspire Capital under the 2020 Purchase Agreement since June 2020. As of **June 30, 2022** **December 31, 2022**, the amount remaining under the 2020 Purchase Agreement was \$18.9 million, which is registered under the Company's shelf registration statement on Form S-3 (File No. 333-239493).

In consideration for entering into the 2020 Purchase Agreement and concurrently with the execution of the 2020 Purchase Agreement, the Company issued to Aspire Capital 212,130 shares of the Company's common stock. The shares of common stock issued as consideration were valued at \$681,000, based on the closing price per share of the Company's common stock on the date the shares were issued. This amount and related expenses of \$50,000, which total approximately \$731,000, were recorded as deferred costs. The unamortized amount of deferred costs related to the 2020 Purchase Agreement of \$578,000 at **June 30, 2022** **December 31, 2022** and **September 30, 2021** **September 30, 2022** is included in other assets on the accompanying unaudited condensed consolidated balance sheets.

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### **Note 10 – Share-based Compensation**

We allocate share-based compensation expense to cost of sales, selling, general and administrative expense, and research and development expense based on the award holder's employment function. For the three and nine months ended **June 30, 2022** **December 31, 2022** and 2021, we recorded share-based compensation expenses as follows:

	Three Months Ended		Nine Months Ended		Three Months Ended	
	June 30,		June 30,		2022	2021
	2022	2021	2022	2021	2022	2021
Cost of sales	\$ 25,275	\$ 15,921	\$ 70,923	\$ 50,548	\$ 64,008	\$ 21,076
Selling, general and administrative	2,052,755	1,444,145	5,036,356	2,719,232	3,612,099	1,395,558
Research and development	832,946	440,019	1,809,066	917,883	1,169,162	463,794
Share-based compensation	\$ 2,910,976	\$ 1,900,085	\$ 6,916,345	\$ 3,687,663	\$ 4,845,269	\$ 1,880,428

We have issued share-based awards to employees and non-executive directors under the Company's approved equity plans. Upon the exercise of share-based awards, new shares are issued from authorized common stock.

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### Equity Plans

On **June 16, 2022**, **In June 2022**, the Company's board of directors adopted the Company's 2022 Employment Inducement Equity Incentive Plan (the "Inducement Plan"). The Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Inducement Plan is used exclusively for the issuance of equity awards to certain new hires who satisfied the requirements to be granted inducement grants under Nasdaq rules as an inducement material to the individual's entry into employment with the Company. The terms of the Inducement Plan are substantially similar to the terms of our 2018 Plan. The Company has reserved 4,000,000 shares of common stock under the Inducement Plan and as of **June 30, 2022** **December 31, 2022**, **3,910,000** **3,587,950** shares remain available for issuance under the Inducement Plan.

In March 2018, the Company's stockholders approved the Company's 2018 Equity Incentive Plan (as amended, the "2018 Plan"). On March 29, 2022, the Company's stockholders approved an increase in the number of shares that may be issued under the 2018 Plan to 18.5 million. As of **June 30, 2022** **December 31, 2022**, **6,297,389** **3,900,900** shares remain available for issuance under the 2018 Plan.

In July 2017, the Company's stockholders approved the Company's 2017 Equity Incentive Plan (the "2017 Plan"). A total of 4.7 million shares are authorized for issuance under the 2017 Plan. As of **June 30, 2022** **December 31, 2022**, **18,767,767** shares remain available for issuance under the 2017 Plan. The 2017 Plan replaced the Company's 2008 Stock Incentive Plan (the "2008 Plan"), and no further awards will be made under the 2008 Plan.

### Stock Options

Each option grants the holder the right to purchase from us one share of our common stock at a specified price, which is generally the closing price per share of our common stock on the date the option is issued. Options generally vest on a pro-rata basis on each anniversary of the issuance date within three years of the date the option is issued. Options may be exercised after they have vested and prior to the specified expiry date provided applicable exercise conditions are met, if any. The expiry date can be for periods of up to ten years from the date the option is issued. The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model based on the assumptions established at that time. The Company accounts for forfeitures as they occur and does not estimate forfeitures as of the option grant date.

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The following table outlines the weighted average assumptions for options granted during the three and nine months ended **June 30, 2022** December 31, 2022 and 2021:

	Three Months Ended		Nine Months Ended		Three Months Ended	
	June 30,		June 30,		December 31,	
	2022	2021	2022	2021	2022	2021
<b>Weighted Average Assumptions:</b>						
Expected volatility	92.58%	78.53%	83.77%	68.88%	98.43%	77.39%
Expected dividend yield	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
Risk-free interest rate	3.01%	1.10%	2.10%	0.64%	4.25%	1.33%
Expected term (in years)	6.0	6.0	6.0	5.9	6.0	6.0
Fair value of options granted	\$ 8.97	\$ 5.98	\$ 6.92	\$ 3.46	\$ 9.17	\$ 5.60

During the three and nine months ended **June 30, 2022** December 31, 2022 and 2021, the Company used historical volatility of our common stock over a period equal to the expected life of the options to estimate their fair value. The dividend yield assumption is based on the Company's recent history and expectation of future dividend payouts on the common stock. The risk-free interest rate is based on the implied yield available on U.S. treasury zero-coupon issues with an equivalent remaining term.

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The following table summarizes the stock options outstanding and exercisable at **June 30, 2022** December 31, 2022:

	Weighted Average			Aggregate	Weighted Average			
	Remaining		Intrinsic		Remaining		Aggregate	
	Number of Shares	Exercise Price Per Share	Contractual Term (years)		Number of Shares	Exercise Price Per Share		
Outstanding at September 30, 2021	10,600,680	\$ 2.84						
Outstanding at September 30, 2022					14,263,470	\$ 5.00		
Granted	4,219,965	\$ 9.61			2,703,800	\$ 11.47		
Exercised	(158,237)	\$ 2.60			(114,234)	\$ 2.25		
Forfeited and expired	(55,334)	\$ 4.56			(4,566)	\$ 9.78		
Outstanding at June 30, 2022	14,607,074	\$ 4.79	7.73	\$ 98,145,668				
Exercisable at June 30, 2022	8,144,463	\$ 2.20	6.63	\$ 74,877,016				
Outstanding at December 31, 2022					16,848,470	\$ 6.06	7.54	
Exercisable at December 31, 2022					9,389,548	\$ 2.69	6.19	\$ 30,099,241
								\$ 28,636,365

The aggregate intrinsic values in the table above are before income taxes and represent the number of in-the-money options outstanding or exercisable multiplied by the closing price per share of the Company's common stock on the last trading day of the quarter ended **June 30, 2022** December 31, 2022 of \$11.30, \$5.28, less the respective weighted average exercise price per share at period end.

The total intrinsic value of options exercised during the **nine** three months ended **June 30, 2022** December 31, 2022 and 2021 was approximately \$1.3 million \$355,000 and \$8.3 million, \$447,000, respectively. Cash received from options exercised during the **nine** three months ended **June 30, 2022** December 31, 2022 and 2021 was approximately \$411,000 \$257,000 and \$1.5 million, \$210,000, respectively.

As of **June 30, 2022** December 31, 2022, the Company had unrecognized compensation expense of approximately \$31.3 \$49.6 million related to unvested stock options. This expense is expected to be recognized over a weighted average period of 2.1 2.2 years.

During the quarter ended June 30, 2021, the Company modified stock options held by an optionee upon resignation from the board of directors. As permitted under the 2018 Plan and with the approval of the Compensation Committee of the Board of Directors, the stock options were modified to accelerate vesting to the date of resignation. The aggregate amount of expense recognized in connection with the modification of stock options for the three and nine months ended June 30, 2021 was approximately \$536,000 and is included in selling, general and administrative expenses on the accompanying unaudited condensed consolidated statements of operations. There was no additional expense recognized related to the modification of stock options during the three or nine months ended June 30, 2022.

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[Stock Appreciation Rights](#)

In connection with the closing of the APP Acquisition, the Company issued stock appreciation rights based on 50,000 and 140,000 shares of the Company's common stock to an employee and an outside director, respectively, that vested on October 31, 2018. The stock appreciation rights have a ten-year term and an exercise price per share of \$0.95, which was the closing price per share of the Company's common stock as quoted on Nasdaq on the trading day immediately preceding the date of the completion of the APP Acquisition. Upon exercise, the stock appreciation rights will be settled in common stock issued under the 2017 Plan. As of **June 30, 2022** **December 31, 2022**, vested stock appreciation rights based on 50,000 shares of common stock remain outstanding.

#### Note 11 - Leases

The Company has operating leases for its office, manufacturing and warehouse space, and office equipment. The Company has a finance lease for office equipment, furniture, and fixtures. The Company's leases have remaining lease terms of less than one year to **five** **seven** years, which include the option to extend a lease when the Company is reasonably certain to exercise that option. Certain of our lease agreements include variable lease payments for common area maintenance, real estate taxes, and insurance or based on usage for certain equipment leases. For one of our office space leases, the Company entered into a sublease, for which it receives sublease income. Sublease income is recognized as a reduction to operating lease costs as the sublease is outside of the Company's normal business operations. This is consistent with the Company's recognition of sublease income prior to the adoption of FASB ASC Topic 842.

In June 2021, the Company executed a lease for its new corporate headquarters in Miami, Florida. The Company is leasing approximately 12,000 square feet of office space for an eight year term, which commenced on March 1, 2022. The space replaced the Company's previous corporate headquarters in Miami, Florida when the existing lease terminated at the end of February 2022. Annual base rent payments are \$58.00 per square foot and are subject to a 3% annual escalation. Based on the terms of the lease agreement, the Company paid a security deposit of approximately \$117,000, which is included in other assets on the accompanying unaudited condensed consolidated balance sheets as of **June 30, 2022** and as of **September 30, 2021**. The Company does not have any leases that have not yet commenced as of **June 30, 2022** **December 31, 2022**.

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The components of the Company's lease cost were as follows for the three and nine months ended **June 30, 2022** **December 31, 2022** and 2021:

	Three Months Ended		Nine Months Ended		Three Months Ended	
	June 30,		June 30,		December 31,	December 31,
	2022	2021	2022	2021	2022	2021
<b>Finance lease cost:</b>						
Amortization of right-of-use assets	\$ —	\$ 2,178	\$ 3,631	\$ 6,535	\$ —	\$ 2,178
Interest on lease liabilities	—	611	403	2,327	—	256
Operating lease cost	285,010	136,140	598,965	408,079	281,451	131,110
Short-term lease cost	11,112	1,863	36,817	5,589	10,101	12,771
Variable lease cost	69,531	48,061	162,287	124,283	50,091	46,019
Sublease income	(44,844)	(44,844)	(134,533)	(134,533)	(44,844)	(44,844)
<b>Total lease cost</b>	<b>\$ 320,809</b>	<b>\$ 144,009</b>	<b>\$ 667,570</b>	<b>\$ 412,280</b>	<b>\$ 296,799</b>	<b>\$ 147,490</b>

The Company paid cash of **\$449,000** **\$228,000** and **\$497,000** **\$153,000** for amounts included in the measurement of operating lease liabilities during the **nine** **three** months ended **June 30, 2022** **December 31, 2022** and 2021, respectively.

The Company's operating lease right-of-use assets and the related lease liabilities are presented as separate line items on the accompanying unaudited condensed consolidated balance sheets as of **June 30, 2022** **December 31, 2022** and **September 30, 2021** **September 30, 2022**.

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Other information related to the Company's leases as of **June 30, 2022** **December 31, 2022** and **September 30, 2021** **September 30, 2022** was as follows:

	June 30, 2022	September 30, 2021	DecemberSeptember	
			31, 2022	30, 2022
<b>Operating Leases</b>				
Weighted-average remaining lease term	6.9	2.9	6.6	6.8
Weighted-average discount rate	7.7%	11.5%	7.6%	7.6%
<b>Finance Leases</b>				
Weighted-average remaining lease term	—	0.4		
Weighted-average discount rate	—	13.9%		

The Company's lease agreements do not provide a readily determinable implicit rate. Therefore, the Company estimates its incremental borrowing rate based on information available at lease commencement in order to discount lease payments to present value.

As of June 30, 2022, maturities of lease liabilities were as follows:

<b>Fiscal year ended September 30,</b>	<b>Operating</b>	<b>Sublease</b>
	<b>Leases</b>	<b>Income</b>
2022	\$ 231,392	\$ 51,203
2023	1,023,701	190,749
2024	930,215	—
2025	925,979	—
2026	788,467	—
Thereafter	2,859,431	—
Total lease payments	6,759,185	<u>\$ 241,952</u>
Less imputed interest	(1,543,153)	
<b>Total lease liabilities</b>	<b>\$ 5,216,032</b>	

#### **Note 12 – Contingent Liabilities**

The testing, manufacturing and marketing of consumer products by the Company and the clinical testing of our product candidates entail an inherent risk that product liability claims will be asserted against the Company. The Company maintains product liability insurance coverage for claims arising from the use of its products. The coverage amount is currently \$30.0 million.

#### Legal Proceedings

On December 5, 2022, a putative class action complaint was filed in federal district court for the Southern District of Florida (Ewing v. Veru Inc., et al., Case No. 1:22-cv-23960) against the Company and certain of its current officers and directors (the "Ewing Complaint"). The Ewing Complaint alleges that certain public statements about sabizabulin as a treatment for COVID-19 between May 11, 2022 and November 9, 2022 violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The Company believes that the allegations asserted in the Ewing Complaint are without merit, and the Company intends to vigorously defend the lawsuit. There can be no assurance that the Company will be successful. At this time, the Company is unable to estimate potential losses, if any, related to the lawsuit.

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#### License and Purchase Agreements

From time to time, we license or purchase rights to technology or intellectual property from third parties. These licenses and purchase agreements require us to pay upfront payments as well as development or other payments upon successful completion of preclinical, clinical, regulatory or revenue milestones. In addition, these agreements may require us to pay royalties on sales of products arising from the licensed or acquired technology or intellectual property. Because the achievement of future milestones is not reasonably estimable, we have not recorded a liability on the accompanying unaudited condensed consolidated financial statements for any of these contingencies.

#### Collaborative Arrangements

On January 31, 2022, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the "Lilly Agreement") with Eli Lilly and Company ("Lilly"). Under the Lilly Agreement, the Company is sponsoring a clinical trial in which both the Company's enobosarm compound and Lilly's compound are being dosed in combination. The Company is conducting the research at its own cost and Lilly is contributing its compound towards the study at no cost to the Company. The parties will continue to hold exclusive rights to all intellectual property relating solely to their own respective compounds. The Company will provide to Lilly copies of clinical data relating to the clinical trial and certain rights to use the clinical data. Veru maintains full exclusive, global commercialization rights to the enobosarm compound.

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The terms of the Lilly Agreement meet the criteria under ASC Topic 808, Collaborative Arrangements ("ASC 808"), as both parties are active participants in the activity and are exposed to the risks and rewards dependent on the commercial success of the activity. ASC 808 does not provide guidance on how to account for the activities under the collaboration, and the Company determined that Lilly did not meet the definition of a customer under ASC 606, Revenue from Contracts with Customers. The Company has concluded that ASC 730, Research and Development, should be applied by analogy. There is no financial statement impact for the Lilly Agreement as the value of the drug supply received from Lilly is offset against the drug supply cost within research and development expense.

#### **Note 13 – Income Taxes**

The Company accounts for income taxes using the liability method, which requires the recognition of deferred tax assets or liabilities for the tax-effected temporary differences between the financial reporting and tax bases of its assets and liabilities, and for net operating loss (NOL) and tax credit carryforwards.

As of **September 30, 2021** **September 30, 2022**, the Company had U.S. federal and state NOL carryforwards of **\$38.8** **\$112.5** million and **\$25.0** **\$50.9** million, respectively, for income tax purposes with \$29.7 million and **\$22.6** **\$28.4** million, respectively, expiring in years **2022** **2023 to 2040** **2024** and **\$9.1** **\$8.8** million and **\$2.4** **\$22.5** million, respectively, which can be carried forward indefinitely. As of **September 30, 2021** **September 30, 2022**, the Company also had U.S. federal research and development tax credit carryforwards of

\$4.4 \$8.5 million, expiring in years 2038 to 2041 2042. The Company's U.K. subsidiary has U.K. NOL carryforwards of \$63.5 \$63.1 million as of September 30, 2021 September 30, 2022, which can be carried forward indefinitely to be used to offset future U.K. taxable income.

The Tax Cuts and Jobs Act of 2017, which was signed into U.S. law in December 2017, eliminated the option to immediately deduct research and development expenditures in the year incurred under Section 174 of the Internal Revenue Code effective for the Company October 1, 2022. The amended provision under Section 174 of the Internal Revenue Code requires us to capitalize and amortize these expenditures over five years, for U.S.-based research, and over 15 years, for foreign-based research. As of December 31, 2022, we recorded a decrease to income tax benefit and an increase to deferred tax assets, before applying a valuation allowance, of approximately \$3.7 million. Because the Company has a full valuation allowance recorded against U.S. deferred tax assets, the net impact to income tax benefit and deferred tax assets is zero.

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A reconciliation of income tax (benefit) expense and the amount computed by applying the U.S. statutory rate of 21% to (loss) income loss before income taxes is as follows:

	Three Months Ended		Nine Months Ended		Three Months Ended	
	June 30,		June 30,		December 31,	
	2022	2021	2022	2021	2022	2021
Income tax (benefit) expense at U.S. federal statutory rates	\$ (4,632,174)	\$ (1,168,845)	\$ (8,931,007)	\$ 1,872,314		
State income tax (benefit) expense, net of federal (benefit) expense	(358,662)	(90,502)	(691,515)	144,971		
Income tax benefit at U.S. federal statutory rates					\$ (7,751,197)	\$ (1,315,724)
State income tax benefit, net of federal benefit						(600,164) (101,875)
Non-deductible expenses	(355,069)	(2,807)	4,860	(2,807)	113,456	257,196
Effect of stock options exercised	(147,570)	53,011	(170,920)	—	83,736	(23,350)
Effect of common stock purchase warrants exercised	—	—	—	(2,038,919)		
Effect of Paycheck Protection Program funds	—	8,784	—	(113,442)		
U.S. research and development tax credit	(1,283,944)	(919,415)	(4,160,374)	(919,415)	(1,090,000)	(1,963,430)
Effect of foreign income tax rates	366,493	(3,716,935)	327,055	(3,744,512)	(80,110)	(29,761)
Effect of global intangible low taxed income	(12,989)	78,626	—	148,383	—	88,267
Change in valuation allowance	6,504,878	2,834,482	13,637,539	1,828,730	9,256,119	3,089,596
Other, net	56,640	50,538	209,170	51,626	(118)	113,736
Income tax expense (benefit)	\$ 137,603	\$ (2,873,063)	\$ 224,808	\$ (2,773,071)		
Income tax (benefit) expense					\$ (68,278)	\$ 114,655

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Significant components of the Company's deferred tax assets and liabilities are as follows:

	June 30, 2022	September 30, 2021	December September	
			31, 2022	30, 2022
<b>Deferred tax assets:</b>				
Federal net operating loss carryforwards	\$ 14,771,226	\$ 8,209,224	\$ 26,379,703	\$ 23,627,461
State net operating loss carryforwards	2,163,558	1,646,827	3,064,102	2,850,956
Foreign net operating loss carryforwards – U.K.	15,861,787	15,875,889	15,927,491	15,773,497
Foreign capital allowance – U.K.	117,709	117,709	128,490	128,490
U.S. research and development tax credit carryforwards	6,921,789	2,761,415	9,571,789	8,481,789
U.S. research and development expense			3,660,867	—
Accrued compensation			1,521,363	1,227,290
Share-based compensation	3,502,093	2,071,838	5,199,290	4,325,354
Interest expense	2,124,706	1,368,042	2,340,375	2,206,484
Change in fair value of derivative liabilities	1,151,454	1,025,425	372,203	220,607
Other, net – U.K.	83,344	83,344	265,631	265,631
Other, net – Malaysia	95,736	100,654	4,988	—
Other, net – U.S.	276,602	203,237	83,284	81,507
Gross deferred tax assets	47,070,004	33,463,604	68,519,576	59,189,066
Valuation allowance for deferred tax assets	(33,217,550)	(19,580,011)	(54,628,571)	(45,372,452)
Net deferred tax assets	13,852,454	13,883,593	13,891,005	13,816,614

Deferred tax liabilities:				
In-process research and development		(882,427)	(882,427)	(882,427)
Covenant not-to-compete		(21,549)	(33,671)	(13,468)
Other, net - Malaysia				(17,641)
Other, net - U.S.		(6,371)	(6,371)	(6,373)
Net deferred tax liabilities		(910,347)	(922,469)	(902,268)
Net deferred tax asset	\$ 12,942,107	\$ 12,961,124	\$ 12,988,737	\$ 12,884,918

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The deferred tax amounts have been classified on the accompanying unaudited condensed consolidated balance sheets as follows:

	June 30, 2022	September 30, 2021	December 31, 2022	September 30, 2022
Deferred tax asset - U.K.	\$ 12,909,797	\$ 12,923,896	\$ 13,047,175	\$ 12,965,985
Deferred tax asset - Malaysia	95,736	100,654	4,988	—
Total deferred tax asset	\$ 13,005,533	\$ 13,024,550	\$ 13,052,163	\$ 12,965,985
Deferred tax liability - U.S.	\$ (63,426)	\$ (63,426)	\$ (63,426)	\$ (63,426)
Deferred tax liability - Malaysia				(17,641)
Total deferred tax liability	\$ (63,426)	\$ (63,426)	\$ (63,426)	\$ (81,067)

## Note 14 - Net (Loss) Income Loss Per Share

Basic net (loss) income loss per common share is computed by dividing net (loss) income loss by the weighted average number of common shares outstanding for the period. Diluted net (loss) income loss per share is computed by dividing net (loss) income by the weighted average number of common shares outstanding during the period after giving effect to all dilutive potential common shares that were outstanding during the period. Dilutive potential common shares consist of the incremental common shares issuable upon the exercise of stock options and stock appreciation rights and common stock purchase warrants as determined under the treasury stock method.

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The following table provides a reconciliation of the net (loss) income per basic and diluted common share outstanding:

	Three Months Ended		Nine Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
Net (loss) income	\$ (22,195,576)	\$ (2,692,866)	\$ (42,753,412)	\$ 11,688,854
Basic weighted average common shares outstanding	80,088,431	79,729,370	80,054,594	75,054,871
Net effect of dilutive instruments:				
Stock options	—	—	—	7,208,123
Stock appreciation rights	—	—	—	44,379
Common stock purchase warrants	—	—	—	499,783
Total net effect of dilutive instruments	—	—	—	7,752,285
Diluted weighted average common shares outstanding	80,088,431	79,729,370	80,054,594	82,807,156
Net (loss) income per basic common share outstanding	\$ (0.28)	\$ (0.03)	\$ (0.53)	\$ 0.16
Net (loss) income per diluted common share outstanding	\$ (0.28)	\$ (0.03)	\$ (0.53)	\$ 0.14

For the nine months ended June 30, 2021, approximately 819,000 potentially dilutive instruments were excluded from the computation of net income per diluted weighted average common share outstanding because their effect would have been antidilutive. Due to our net loss for the three and nine months ended June 30, 2022 and three months ended June 30, 2021, periods presented, all potentially dilutive instruments were excluded because their inclusion would have been anti-dilutive. See Notes 9 and Note 10 for a discussion of our potentially dilutive instruments, common shares.

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### Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

#### Overview

Veru is a biopharmaceutical company focused on developing novel medicines with a drug development program for the treatment of hospitalized COVID-19 and other viral and patients at high risk for acute respiratory distress syndrome (ARDS)-related diseases and other viral-related ARDS and for the management of advanced breast and prostate cancers. The Company also has cancers, as well as a sexual health program which includes two FDA-approved products, the FC2 Female Condom® (Internal Condom) and ENTADFI™ (finasteride and tadalafil) capsules for sexual health.

**Biopharmaceuticals oral use, for the treatment of benign prostatic hyperplasia (BPH).**

#### Infectious disease franchise: Disease Program:

The Company opportunistically developed sabizabulin 9mg, which has both broad anti-inflammatory and antiviral activities, properties, as a two-pronged approach to the treatment of COVID-19 viral infection in hospitalized moderate to severe hospitalized COVID-19 patients who are at high risk for ARDS and death.

Phase 3 COVID-19 registration trial – Sabizabulin 9mg We discovered that sabizabulin, which is being developed for cancer indications for the treatment of COVID-19 viral infection, and the subsequent debilitating inflammatory effects that can lead to ARDS and death. The Company has completed positive Phase 2 and positive Phase 3 COVID-19 clinical trials evaluating sabizabulin in hospitalized moderate to severe COVID-19 patients. Sabizabulin is an oral, first-in-class, new chemical entity, microtubule disruptor that has dual anti-inflammatory patients at high risk for ARDS and antiviral properties, death. The Phase 3 COVID-19 clinical study was a double-blind, randomized, placebo-controlled clinical trial conducted study in approximately 210 204 hospitalized moderate to severe COVID-19 patients who were at high risk for ARDS and death. The primary endpoint was the proportion of deaths patients that died by Day 60. The FDA granted Fast Track designation to the Company's COVID-19 program in January 2022. In April 2022, Based on a planned interim analysis of the first 150 patients randomized, into the study was conducted and the Independent Data Monitoring Committee unanimously voted to stop recommended that the Phase 3 COVID-19 clinical study be stopped for clear evidence of clinical efficacy benefit. Sabizabulin and identified no safety concerns. In the interim analysis, treatment versus placebo with sabizabulin 9 mg once daily resulted in both a clinically meaningful and statistically significant 55.2% relative reduction in deaths (p=0.0042) and no safety issues were identified, compared to placebo.

On May 10, 2022, the Company had a pre-Emergency Use Authorization pre-emergency use authorization (EUA) meeting with the FDA to discuss next steps including the submission of an EUA application regarding for sabizabulin for COVID-19, COVID-19 treatment. The outcome of this meeting was: (i) the FDA agreed that no additional efficacy studies were required to support an EUA application or a new drug application (NDA); and (ii) the FDA agreed that no additional safety data was required to support an EUA application and that collection of safety data under the EUA may satisfy the safety requirement for an NDA. The FDA agreed that the request for the EUA is supported by efficacy and safety from our positive Phase 3 COVID-19 study in hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS and death and no additional clinical trials are may be required to support an NDA submission. On June 7, 2022, the Company submitted a request for FDA emergency use authorization, authorization for sabizabulin in adult hospitalized moderate to severe COVID-19 patients at high risk for ARDS and death. On July 6, 2022, the Company announced the publication of the clinical results from the Phase 3 COVID-19 study evaluating the efficacy and safety of oral sabizabulin in The New England Journal of Medicine Evidence. On July 25, 2022 November 9, 2022, the Company announced that the United Kingdom's Medicines and Healthcare Products Regulatory Agency had informed the Company that it considers that the currently available safety and efficacy data will support an expedited FDA's Pulmonary-Allergy Drugs Advisory Committee (PADAC) met to review of the marketing authorization sabizabulin for the Company's sabizabulin treatment EUA in hospitalized moderate to severe COVID-19 patients who are at high risk for ARDS when the application is submitted. On July 27, 2022, the Company announced ARDS. The advisory committee voted 8-5 that the European Medicines Agency's Emergency Task Force had informed the Company that it had initiated the review known and potential benefits of sabizabulin when used for the treatment of adult patients hospitalized with COVID-19 patients at high risk for of ARDS do not outweigh the known and potential risks of sabizabulin. However, there was additional discussion around the clinical trial design aspects of a potential confirmatory Phase 3 COVID-19 clinical trial as a requirement or condition for emergency use authorization. The FDA considers the input of the FDA advisory committee as part of their review of the EUA, but the advisory committee vote is not binding as the FDA makes the final decision on the request for EUA application.

On January 30, 2023, the White House Office of Management and Budget announced that the Biden administration plans to terminate the COVID-19 national and public health emergencies on May 11, 2023 (the "May 11 Termination"). The FDA's authority to issue emergency use authorizations stems from a separate emergency declaration by the Secretary of the Department of Health and Human Services regarding medical countermeasures in the European Union Member States, fight against COVID-19. This separate HHS emergency currently remains in effect. The FDA announced on January 31, 2023 that the May 11 Termination would not impact the FDA's ability to authorize new treatments for emergency use, that existing EUAs would remain in effect and that it may continue to issue new EUAs when criteria for issuance are met. Currently, we believe our EUA for sabizabulin is still under consideration by the FDA; however, we do not know when the FDA will act on our EUA.

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The UK's Medicine and Healthcare Products Regulatory Agency (MHRA) informed the Company on July 25, 2022, that the sabizabulin marketing authorization application will receive expedited review. On July 27, 2022, sabizabulin triggered Article 18 in the European Union (EU) in which the European Medicines Agency (EMA) will evaluate sabizabulin to allow emergency use drug access to the EU Member States. On August 22, 2022, Australia's Therapeutic Goods Administration (TGA) determined that sabizabulin treatment in hospitalized COVID-19 patients at high risk for ARDS qualifies for an expedited, provisional registration regulatory pathway. Sabizabulin for COVID-19 is also currently under regulatory review for potential emergency or conditional authorization by Canada's Health Canada, South Korea's Ministry of Food and Drug Safety, and Switzerland's Swissmedic. With the positive Phase 3 clinical results of sabizabulin in hospitalized moderate to severe COVID-19 patients at high risk for ARDS, we want to focus the clinical development of sabizabulin, a broad spectrum antiviral and anti-inflammatory agent, as a treatment for additional indications in COVID-19-related ARDS, Influenza related ARDS, and other viral-associated ARDS. The development program may include a confirmatory Phase 3 clinical study in hospitalized COVID-19 patients, if required, to support the full regulatory applications in multiple regions, including the U.S. and Europe.

## **Oncology program: Program:**

The Company's breast cancer drug pipeline has three four clinical development programs for two drugs: enobosarm, an oral selective androgen receptor targeting agonist, and sabizabulin, an oral cytoskeleton microtubule disruptor.

**Phase 3 ARTEST clinical study – Enobosarm monotherapy as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (high AR nuclei staining). cancer.** We are enrolling the Phase 3 multicenter, international, open label, and randomized (1:1) ARTEST registration clinical trial design to evaluate the efficacy and safety of enobosarm monotherapy versus physician's choice of either exemestane ± everolimus or a SERM as the active comparator for the treatment of AR+ ER+ HER2- metastatic breast cancer in approximately 210 patients with high sufficient AR nuclei staining in their breast cancer tissue who have previously received had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor. We have identified that patients who have higher levels androgen receptor sufficient AR nuclei staining in their breast cancer tissue are most likely to respond to enobosarm. Based on the recommendation of the FDA to have a companion diagnostic test to determine the patient's AR status, we have partnered with Roche/Ventana Diagnostics, a global oncology diagnostics company, who is working to develop and, if approved, commercialize a companion diagnostic AR immunohistochemistry test. In January 2022, our enobosarm program received a Fast Track designation by the FDA.

**Phase 3 ENABLAR-2 clinical study – Enobosarm + abemaciclib combination as a 2nd line treatment of AR+ER+HER2- metastatic breast cancer (high AR nuclei staining).** We are enrolling a Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the efficacy and safety of enobosarm plus abemaciclib combination therapy versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have previously received first line palbociclib (a CDK4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and have a high AR nuclei staining in their breast cancer tissue. We plan to enroll approximately 186 subjects in this Phase 3 clinical study. We have a clinical trial collaboration and supply agreement with Eli Lilly and Company ("Lilly") for the ENABLAR-2 Phase 3 clinical study. Under the terms of the non-exclusive clinical trial collaboration and supply agreement, Veru is responsible for conducting the clinical trial, while Lilly will supply abemaciclib for the study. Veru maintains full exclusive, global rights to enobosarm.

**Planned Phase 2b clinical study – Sabizabulin monotherapy as a 3rd line treatment of AR+ER+HER2- metastatic breast cancer (low AR nuclei staining). cancer.** We also intend to conduct a Phase 2b clinical study of sabizabulin, a novel oral cytoskeleton disruptor, for the treatment of AR+ ER+ HER2- metastatic breast cancer in patients with a low sufficient AR nuclei staining. The Phase 2b clinical trial will be an open label, multicenter, and randomized (1:1) study evaluating the efficacy and safety of sabizabulin 32mg monotherapy versus physician's choice of either exemestane ± everolimus or a SERM as the active comparator for the treatment of ER+ HER2- metastatic breast cancer in approximately 200 patients with a low level of sufficient AR nuclei staining in their breast cancer tissue who have previously received had tumor progression on a nonsteroidal aromatase inhibitor, fulvestrant, and a CDK4/6 inhibitor.

**Phase 3 clinical study – Enobosarm + abemaciclib combination as a 2nd line treatment of AR+ER+HER2- metastatic breast cancer.** We are enrolling a Phase 3 multicenter, open label, randomized (1:1), active control clinical study, named ENABLAR-2 to evaluate the efficacy and safety of enobosarm plus abemaciclib combination therapy versus an alternative estrogen blocking agent (fulvestrant or an aromatase inhibitor) in subjects with AR+ ER+ HER2- metastatic breast cancer who have failed first line palbociclib (a CDK4/6 inhibitor) plus an estrogen blocking agent (non-steroidal aromatase inhibitor or fulvestrant) and have sufficient AR nuclei staining in their breast cancer tissue. We have completed Stage 1, which assessed and demonstrated the pharmacokinetics and tolerability of the enobosarm and abemaciclib combination. In Stage 2 of this Phase 3 study, we plan to enroll approximately 183 subjects. In January 2022, the Company entered into a clinical trial collaboration and supply agreement through which Eli Lilly and Company supplies abemaciclib for the ENABLAR-2 trial.

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**The Company's prostate cancer drug pipeline includes sabizabulin, VERU-100 and zuclofimiphene citrate.**

**Sabizabulin 32mg for the treatment of metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer. cancer-**

**Phase 1b/2 clinical studies to determine maximum tolerated dose and recommended dosing of sabizabulin.** We are completing the Phase 1b open label clinical trial of sabizabulin in 39 men with metastatic castration resistant and androgen receptor targeting agent resistant prostate cancer ± taxane chemotherapy and the Phase 2 clinical study in 41 men with metastatic castration resistant prostate cancer who have also become resistant to at least one androgen receptor targeting agent, but prior to proceeding to IV chemotherapy. In the Phase 1b/2 studies, sabizabulin was both well tolerated and demonstrated promising preliminary efficacy data.

**Phase 3 VERACITY clinical study.** We are currently enrolling the Phase 3 VERACITY registration study evaluating sabizabulin 32mg in men approximately 245 men who have metastatic castration resistant prostate cancer and who had tumor progression while receiving at least one androgen receptor targeting agent, but prior to IV chemotherapy.

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**VERU-100, long-acting GnRH antagonist subcutaneous depot, for the treatment of advanced hormone sensitive prostate cancer. cancer-**

**Phase 2 dose finding clinical study.** We are currently enrolling a study to determine optimal dose of VERU-100 in approximately 45 men with advance hormone sensitive prostate cancer.

**Planned Phase 3 registration clinical study.** If the Phase 2 trial is successful, then, and as discussed with and agreed upon by the FDA, the Phase 3 clinical trial will be a single arm, multicenter, open-label study in approximately 100 men with hormone sensitive advanced prostate cancer using the achievement and maintenance of castration levels of testosterone as the primary endpoint.

**Zuclofimiphene citrate, estrogen receptor agonist, for the treatment of hot flashes caused by prostate cancer hormonal therapies in men with advanced prostate**

**cancer: cancer-**

**Planned Phase 2b zuclomiphene clinical study.** The Company reported positive dose finding Phase 2 study in January 2020. The Company plans to further optimize the dosing schedule of zuclomiphene citrate in a Phase 2b study.

#### **Sexual Health Program**

The Company's sexual health program includes two FDA-approved products: FC2, for the dual protection against unplanned pregnancy and the transmission of sexually transmitted infections and ENTADFI™ (finasteride and tadalafil). ENTADFI was approved by, for the FDA in December 2021 as a new oral treatment for BPH, or an enlarged prostate gland. The co-administration of tadalafil and finasteride has been shown to provide faster and more effective treatment of benign prostatic hyperplasia than finasteride alone without causing sexual adverse effects. The FDA had been reviewing our product release criteria from our contract manufacturing facility and has now given its approval. We have now initiated the U.S. commercial launch and availability of ENTADFI. We plan to market ENTADFI to healthcare providers and patients via telemedicine and internet pharmacy services (including through a collaboration with GoodRx) and we expect that distribution will also be conducted through the traditional pharmaceutical distribution channels. We will plan to augment our marketing and sales efforts by seeking partners in the U.S. and outside the U.S. BPH.

The Company sells FC2 Female Condom/FC2 Internal Condom® (FC2). FC2 is sold in both the commercial sector and in the public health sector both in the U.S. and globally. In the U.S., FC2 is available by prescription through multiple telemedicine and internet pharmacy channels as well as retail pharmacies. The Company has launched its own dedicated direct to patient telemedicine and pharmacy services portal/platform to continue to drive sales growth. FC2 is also available to public health sector entities such as state departments of health and 501(c)(3) organizations. In the global public health sector, the Company markets FC2 to entities, including ministries of health, government health agencies, U.N. agencies, nonprofit organizations and commercial partners, that work to support and improve the lives, health and well-being of women around the world.

All ENTADFI™ (finasteride and tadalafil) capsules for oral use was approved by the FDA as a new treatment for BPH, or an enlarged prostate gland. The co-administration of tadalafil and finasteride has been shown to provide faster and more effective treatment of BPH than finasteride alone without causing unwanted sexual side effects. ENTADFI treats BPH with low potential for adverse sexual side effects, and we believe that ENTADFI being one single pill will help increase drug compliance whereas poor compliance with a BPH medicine could lead to an increased chance of acute urinary retention, urosepsis, and death. We have now initiated the U.S. commercial launch of ENTADFI. The launch of ENTADFI has faced challenging market conditions in what has become a genericized market. As a result, the potential market size for ENTADFI is uncertain.

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Most of the Company's net revenues are currently derived from sales of FC2 in the commercial and public health sectors.

In February 2022, the Company received a tender award to supply 57% of a tender covering up to 120 million female condoms over three years in the Republic of South Africa. The Company has received its first orders and is manufacturing units under this tender award. In October 2020, the Company was awarded up to 20 million units through its distributor in Brazil under the new Brazil female condom tender. The Company began shipping units under this tender award in the first quarter of fiscal 2021 and we have shipped approximately 9.7 million units through June 30, 2022. The Company does not anticipate any additional shipments under this tender in Brazil.

#### **Consolidated Operations:**

**Revenues.** Most of the Company's net revenues during the nine months ended June 30, 2022 and 2021 were primarily derived from sales of FC2 in the U.S. prescription channel and global public health sector. The Company has also had begun to recognize revenues from sales of PREBOOST® (Roman Swipes) during the nine months ended June 30, 2021 through the date the PREBOOST® business was sold on December 8, 2020, ENTADFI. These sales are recognized upon shipment or delivery of the product to the customers depending on contract terms.

The Company's most significant customers to date have been customer base is telemedicine providers in the U.S. who sell into the prescription channel and global public health sector agencies who purchase and/or distribute FC2 for use in preventing the transmission of HIV/AIDS and/or family planning.

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We have begun to see an increase in U.S. public sector revenues.

The Company manufactures FC2 in a leased facility located in Selangor D.E., Malaysia, resulting in a portion of the Company's operating costs being denominated in foreign currencies. While a significant portion of the Company's future unit sales are likely to be in foreign markets, all sales are denominated in the U.S. dollar. Effective October 1, 2009, the Company's U.K. and Malaysia subsidiaries adopted the U.S. dollar as their functional currency, further reducing the Company's foreign currency risk.

**Operating Expenses.** The Company manufactures FC2 at its Malaysian facility. The Company's cost of sales consists primarily of direct material costs, direct labor costs and indirect production and distribution costs. Direct material costs include raw materials used to make FC2, principally a nitrile polymer. Indirect production costs include logistics, quality control and maintenance expenses, as well as costs for electricity and other utilities. All the key components for the manufacture of FC2 are essentially available from either multiple sources or multiple locations within a source.

We have recently seen an increase in the cost of the nitrile polymer used to produce FC2, as well as transportation, and may experience increases in other raw material logistic, and energy costs due to the impact of COVID-19 and increased inflation. Additionally, increases in Malaysian minimum wages will increase our production costs and those of our suppliers. Our costs of sales and gross margins may be adversely impacted if we are unable to pass along cost increases to our customers.

Conducting research and development is central to our business model, infectious disease and oncology programs. The Company has multiple products under clinical development and management routinely evaluates and prioritizes each product in its portfolio of products. Advancement is limited to available working capital and management's understanding of the prospects for each product. If future prospects do not meet management's strategic goals, advancement may be discontinued. We have invested and expect

to continue to invest significant time and capital in our research and development operations. Our research and development expenses were \$18.1 million and \$11.2 million for the three months ended June 30, 2022 December 31 2022 and 2021, respectively, and \$43.8 million and \$24.4 million for the nine months ended June 30, 2022 and 2021, respectively. We expect to continue this trend of increased expenses relating to research and development due to advancement of multiple drug candidates.

#### COVID-19 Environment

In December 2019, a novel strain of coronavirus was reported to have emerged in Wuhan, China. COVID-19, the disease caused by the coronavirus, has since spread to over 100 countries, including every state in the United States. On March 11, 2020, the World Health Organization declared COVID-19 a pandemic, and on March 13, 2020, the United States declared a national emergency with respect to the COVID-19 outbreak.

In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, the United Kingdom and Malaysia, have imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. In addition, and in an attempt to slow the rapid growth of the COVID-19 infection rate, many governments around the world, including in the United States at the federal, state and local levels as well as in the United Kingdom and Malaysia, have from time to time imposed mandatory sheltering in place and social distancing restrictions that severely limit the ability of its citizens to travel freely and to conduct activities.

The COVID-19 pandemic has substantially impacted the global healthcare system, including the conduct of clinical trials. Many healthcare systems have restructured operations to prioritize caring for those suffering from COVID-19 and to limit or cease other activities. The severe burden on healthcare systems caused by this pandemic has also impaired the ability of many research sites to start new clinical trials or to enroll new patients in clinical trials. The imposed mandatory sheltering in place and social distancing restrictions may delay the recruitment of patients and impede their ability to effectively participate in such trials. Significant fees may also be owed to contract research organizations associated with starting and stopping clinical trials, typically more so than delaying the start of a clinical trial.

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To date, COVID-19 has not impacted the Company's ability to supply product demand for FC2. Since the start of the pandemic, we have, from time to time, experienced some temporary disruptions to our manufacturing facility due to the implementation of government policies. Most recently, on June 1, 2021, the Malaysian government issued a nationwide lockdown order placing limitations on social and economic activity in the country. The Company was able to secure the required approvals, as a health product, to continue to partially operate by reducing the number of employees physically allowed in the facilities to 60% of the total workforce. On July 3, 2021, the lockdown was strengthened in the region in which the Company operates and the Company entered into a two-week period ceasing all operations, in common with similar manufacturing businesses. On July 19, 2021, after allowing some time for staff testing, operations resumed at the required levels of 60% of the total workforce. The Company has partially mitigated the disruption to production by changing staffing patterns. From time to time, we have temporarily paused operations as part of our contact tracing protocols and to allow for cleaning and disinfection of our production facility.

The Company has enrolled manufacturing staff in a vaccination program. 100% of the staff have received two doses of vaccination and more than 90% of staff have also received a booster. This has allowed shift patterns to return to normal and the facility is allowed to operate at 100% capacity under the current Malaysia control orders.

The Company has had and believes it continues to have a sufficient quantity of FC2 inventory both inside and outside of Malaysia to satisfy expected customer demand. The closure and reduced operating capacity did not have a material impact to the Company's consolidated operating results in fiscal 2021 or the first half of fiscal 2022 and we do not expect them to have a material impact on the Company's consolidated operating results in foreseeable future periods. The Company continues to operate enhanced health and safety protocols to protect the employees at its Malaysian facility, to respond in the event an employee at the facility is determined to have tested positive for COVID-19, and to mitigate the impact of COVID-19 on the Company's Malaysian manufacturing operations. However, no such measures can eliminate risks relating to the COVID-19 pandemic, and if the Company's Malaysian manufacturing facility is subject to future government mandates to counter COVID-19 or encounters labor or raw material shortages, transportation delays or other issues, our ability to supply product to our customers could be disrupted.

The sole supplier of the nitrile polymer sheath for FC2 also produces surgical gloves and has at times prioritized their production during the COVID-19 pandemic and may continue to do so, which could disrupt the Company's supply of a critical raw material. Malaysian ports are currently open for shipment but at reduced capacity, and the Company may also encounter issues shipping product into key markets or through freight or other carriers. To mitigate these factors, the Company continues to build strategic stock to ensure supply is available during a period of potential disruption. The COVID-19 pandemic and related economic disruption may also adversely affect customer demand for FC2. For example, sales of FC2 could be impacted in the U.S. prescription channel if insurance coverage is affected by job losses and in the global public health sector if governments delay future tenders or reduce spending on female condoms due to financial strains or changed spending priorities caused by the COVID-19 pandemic. The COVID-19 pandemic did not have a material net impact on our consolidated operating results during the three or nine months ended June 30, 2022.

Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations, and on the global economy. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels as a result of uncertainties, including the extent and rate of the spread of the virus that continue to fluctuate, the potential for additional peaks in infection rates, and the timing and availability of vaccines, treatments or cures to slow and eventually stop the spread. We do not yet know the full extent of any impact on our business or our operations; however, we will continue to monitor the COVID-19 situation and its impact on our business closely and expect to reevaluate the timing of our anticipated clinical trials as the impact of COVID-19 on our industry becomes clearer.

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### [Results of Operations](#)

THREE MONTHS ENDED **JUNE 30, DECEMBER 31, 2022** COMPARED TO THREE MONTHS ENDED **JUNE 30, DECEMBER 31, 2021**

The Company generated net revenues of **\$9.6** **\$2.5** million and net loss of **\$22.2** **\$36.8** million, or **(\$0.28)** **(\$0.46)** per basic and diluted common share, for the three months ended **June 30, 2022** **December 31, 2022**, compared to net revenues of **\$17.7** **\$14.1** million and net loss of **\$2.7** **\$6.4** million, or **(\$0.03)** **(\$0.08)** per basic and diluted common share, for the three months ended **June 30, 2021** **December 31, 2021**. Net revenues decreased **46%** **82%** compared to the prior period.

**All** Most of the Company's net revenues for the three months ended **June 30, 2022** **December 31, 2022** and 2021 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a decrease in the FC2 average sales price per unit of **6%** **72%**. The principal factor for the decrease in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the **U.S. prescription channel** **global public health sector** representing **70%** **93%** of total FC2 net revenues in the current year period **compared to 76%** and the **U.S. prescription channel** representing **82%** of total FC2 net revenues in the prior year period. **Sales to the global public health sector** are at a lower sales price per unit. The Company experienced a decrease compared to the prior year period of **50%** **99%** in FC2 net revenues in the U.S. prescription channel and a decrease compared to the prior year period of **31%** **9%** in FC2 net revenues in the global public health sector. The decrease in FC2 net revenues in the U.S. prescription channel is primarily due to lower volume from telemedicine customers as a result of business challenges they **experienced**, **have been experiencing**, which resulted in a slowdown in orders during the **current quarter**, **recent quarters**. We **expect** **their historical** **are working to restore** **ordering and utilization patterns to resume** in future **quarters**, although there is **uncertainty** **periods based on growing awareness and demand through increased FC2 marketing efforts, as to timing of the resumption**. The reduction **well as on-going discussions** **with new distribution partners in the global telehealth sector**. We are also working to generate additional revenues through our telehealth platform. We have begun to see an increase in **U.S. public health sector** is primarily due to sales in the fiscal 2021 period related to the **Brazil and South Africa tenders**, which did not repeat in the fiscal 2022 period. **revenues through two new agreements recently executed**.

Significant quarter-to-quarter variances in **sales in the Company's results** **global public health sector** have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for FC2. The Company is also currently seeing pressure on pricing for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector.

Cost of sales decreased to **\$2.5** **\$1.8** million in the three months ended **June 30, 2022** **December 31, 2022** from **\$3.8** **\$2.3** million in the three months ended **June 30, 2021** **December 31, 2021** due to the decrease in unit sales.

Gross profit decreased to **\$7.1** **\$0.7** million in the three months ended **June 30, 2022** **December 31, 2022** from **\$13.9** **\$11.8** million in the three months ended **June 30, 2021** **December 31, 2021**. Gross profit margin for the fiscal **2022** **2023** period was **74%** **28%** of net revenues, compared to **79%** **84%** of net revenues for the fiscal **2021** **2022** period. The decrease in the gross profit and gross profit margin is primarily due to **higher** **the decrease in** FC2 net revenues in the U.S. prescription channel, **in the prior period**, which had **higher profit margins**, **reduced production as a result of lower sales volume, which results in a higher cost per unit**.

Research and development expenses increased to **\$18.1** **\$18.7** million in the three months ended **June 30, 2022** **December 31, 2022** from **\$11.2** **\$10.1** million in the same period in fiscal **2021**, **2022**. The increase is primarily due to increased costs associated with the multiple in-process research and development projects, mainly for the Phase 3 COVID-19 registration trial and manufacturing costs of **\$8.0** million for pre-launch inventory, and increased personnel **costs**. **During** **costs**, resulting from increased headcount and an increase in the **third quarter** **fair value of** fiscal 2022, the Company had four Phase 3 clinical trials and two Phase 2 clinical trial ongoing with additional clinical trial initiations planned, compared to two Phase 3 clinical trials and two Phase 2 clinical trials during the third quarter of fiscal 2022. This clinical trial activity has resulted in increased costs, **share-based compensation**.

Selling, general and administrative expenses increased to **\$10.8** **\$17.5** million in the three months ended **June 30, 2022** **December 31, 2022** from **\$5.6** **\$6.7** million in the three months ended **June 30, 2021** **December 31, 2021**. The increase is due primarily to **commercialization costs** of **\$8.4** million related to preparations for the following: an increase **potential launch of** **sabizabulin for COVID-19** **incurred in compensation costs**, resulting from increased personnel **the first quarter of fiscal 2023** and an increase in **salaries for a cost-of-living adjustment**; increased **share-based compensation costs** to **\$3.6** million from **\$1.4** million, resulting from an increase in **increased headcount and an increase in the fair value of stock options due granted**, which was **\$9.17** per share weighted average in the first quarter of fiscal 2023 compared to **increased volatility** **\$5.60** per share weighted average in **our stock price**; and additional costs associated with the **commercialization of ENTADFI™**, **commercialization costs related to preparations for the potential launch of** **sabizabulin for COVID-19**, and the **launch of the Company's own dedicated direct to patient telemedicine and pharmacy services portal/platform for FC2**, **same period in fiscal 2022**.

Interest expense, which is related to **accretion of the Credit Agreement and liability for the Residual Royalty Agreement**, was **\$0.9** million in the three months ended **December 31, 2022**, which is comparable with **\$1.2** million in the three months ended **June 30, 2022**, which is comparable with **\$1.3** million **December 31, 2021**. The decrease relates to a decrease in the three months ended **June 30, 2021**.

projected FC2 sales.

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### [Income](#)

Expense associated with the change in fair value of the embedded derivatives related to the **Credit Agreement and Residual Royalty Agreement** was **\$0.9** **\$0.7** million in the three months ended **June 30, 2022** **December 31, 2022**, compared to expense of **\$1.3** **\$0.2** million in the three months ended **June 30, 2021** **December 31, 2021**. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax **expense** **benefit** in the **third** **first** quarter of fiscal **2022** **2023** was **\$138,000**, **\$68,000**, compared to income tax **benefit** **expense** of **\$2.9** **\$0.1** million in the **third** **first** quarter of fiscal **2021**, **2022**. The change is due primarily to a tax benefit recorded in the **prior year** **current period** resulting from an adjustment of the value of U.K. net operating losses due

to an increase in the U.K. tax rates from 19% to 25%. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. has no effect on income tax expense.

#### NINE MONTHS ENDED JUNE 30, 2022 COMPARED TO NINE MONTHS ENDED JUNE 30, 2021

The Company generated net revenues of \$36.8 million and net loss of \$42.8 million, or \$(0.53) per basic and diluted common share, for the nine months ended June 30, 2022, recognized by our U.K. subsidiary compared to net revenues of \$45.6 million and net income of \$11.7 million, or \$0.16 per basic common share and \$0.14 per diluted common share, for the nine months ended June 30, 2021. Net revenues decreased 19% over the prior period.

All of the Company's net revenues for the nine months ended June 30, 2022 and most of the Company's net revenues for the nine months ended June 30, 2021 were derived from sales of FC2 in the U.S. prescription channel and global public health sector. There was a 47% decrease in total FC2 unit sales and an increase in FC2 average sales price per unit of 54%. The principal factor for the increase in the FC2 average sales price per unit compared to prior period was the change in the sales mix with the U.S. prescription channel representing 81% of total FC2 net revenues in the current year period compared to 74% of total FC2 net revenues in the prior year period. The Company experienced a decrease compared to the prior year period of 9% in FC2 net revenues in the U.S. prescription channel and a decrease compared to the prior year period of 42% in FC2 net revenues in the global public health sector. The decrease in FC2 net revenues in the U.S. prescription channel is due to lower volume from telemedicine customers as a result of business challenges they experienced, which resulted in a slowdown in orders during the current quarter. We expect their historical ordering patterns to resume in future quarters, although there is uncertainty as to timing of the resumption. The reduction in the global public health sector is primarily due to sales in the fiscal 2021 period related to the Brazil and South Africa tenders, which did not repeat in the fiscal 2022 period. Results for the nine months ended June 30, 2021 included net revenues of \$0.9 million related to the PREBOOST® business before the sale of such business in December 2020.

Significant quarter-to-quarter variances in the Company's results have historically resulted from the timing and shipment of large orders rather than from any fundamental changes in the business or the underlying demand for FC2. The Company is also currently seeing pressure on pricing for FC2 by large global agencies and donor governments in the developed world. As a result, the Company may continue to experience challenges for revenue from sales of FC2 in the global public health sector.

Cost of sales decreased to \$6.7 million in the nine months ended June 30, 2022 from \$10.0 million in the nine months ended June 30, 2021 due to the decrease in unit sales.

Gross profit decreased to \$30.1 million in the nine months ended June 30, 2022 from \$35.6 million in the nine months ended June 30, 2021. Gross profit margin for the fiscal 2022 period was 82% of net revenues, compared to 78% of net revenues for the fiscal 2021 period. The increase in the gross profit and gross profit margin is primarily due to the increase in FC2 net revenues in the U.S. prescription channel as a percentage of total net revenues, which have higher profit margins.

Research and development expenses increased to \$43.8 million in the nine months ended June 30, 2022 from \$24.4 million in the same period in fiscal 2021. The increase is primarily due to increased costs associated with the multiple in-process research and development projects, mainly for the Phase 3 COVID-19 registration trial, the Phase 3 VERACITY clinical study, and the Phase 3 ARTEST study; as well as increased personnel costs. During the nine months ended June 30, 2022, the Company had four Phase 3 clinical trials and two Phase 2 clinical trial ongoing with additional clinical trial initiations planned, compared to two Phase 3 clinical trials and three Phase 2 clinical trials during the third quarter of fiscal 2022.

This clinical trial activity has resulted in increased costs.

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Selling, general and administrative expenses increased to \$24.8 million in the nine months ended June 30, 2022 from \$14.7 million in the nine months ended June 30, 2021. The increase is due primarily to the following: an increase in compensation costs, resulting from increased personnel and an increase in salaries for a cost-of-living adjustment; increased share-based compensation costs, resulting from an increase in headcount and an increase in the fair value of stock options due to increased volatility in our stock price; and additional costs associated with the commercialization of ENTADFI™, commercialization costs related to preparations for the potential launch of sabizabulin for COVID-19, and the launch of the Company's own dedicated direct to patient telemedicine and pharmacy services portal/platform for FC2.

During the nine months end June 30, 2021, we recorded a pre-tax gain on sale of the Company's PREBOOST® business of \$18.4 million. See Note 2 to the financial statements included in this report for additional information.

Interest expense, which is related to the Credit Agreement and Residual Royalty Agreement, was \$3.6 million in the nine months ended June 30, 2022, which is comparable to \$3.7 million in the nine months ended June 30, 2021.

Expense associated with the change in fair value of the embedded derivatives related to the Credit Agreement and Residual Royalty Agreement was \$0.6 million in the nine months ended June 30, 2022, compared to expense of \$2.0 million in the nine months ended June 30, 2021. The liabilities associated with embedded derivatives represent the fair value of the change of control provisions in the Credit Agreement and Residual Royalty Agreement. See Note 3 and Note 8 to the financial statements included in this report for additional information.

Income tax expense in the nine months ended June 30, 2022 was \$224,000, compared to income tax benefit of \$2.8 million in the nine months ended June 30, 2021. The change is due primarily to a tax benefit recorded expense in the prior year period resulting from an adjustment of the value of U.K. net operating losses due to an increase in the net income recognized by our U.K. tax rates from 19% to 25% subsidiary. The U.S. continues to have a full valuation allowance on its deferred tax assets; therefore, activity in the U.S. has no effect on income tax expense.

#### Liquidity and Sources of Capital

##### Liquidity

Our cash and cash equivalents on hand at June 30, 2022 December 31, 2022 was \$100.6 \$46.9 million, compared to \$122.4 \$80.2 million at September 30, 2021 September 30, 2022. At June 30, 2022 December 31, 2022, the Company had working capital of \$100.6 \$32.9 million and stockholders' equity of \$116.9 \$49.1 million compared to working capital of \$136.0 \$63.3 million and stockholders' equity of \$152.3 \$80.8 million as of September 30, 2021 September 30, 2022. The decrease in working capital is primarily due to the decrease in

cash on hand, related to our increased spend on research and development costs, and an increase in accounts payable and accrued research and development drug commercialization costs.

We anticipate that we will continue to consume cash as we develop and commercialize our drug candidates. Because of the numerous risks and uncertainties associated with the development of pharmaceutical products, we are unable to estimate the exact amounts of capital outlays and operating expenditures necessary to fund development of our drug candidates and obtain regulatory approvals. Our future capital requirements will depend on many factors. See Part II, Item 1A, "Risk Factors - We may need to seek and secure significant funding through financings or from other sources to effectively commercialize sabizabulin as a treatment for COVID-19" below in this Quarterly Report on Form 10-Q, and Part I, Item 1A, "Risk Factors - Risks Related to Our Financial Position and Need for Capital" in the Company's Annual Report on Form 10-K for the fiscal year ended September 30, 2021 September 30, 2022 for a description of certain risks that will affect our future capital requirements.

The Company believes its current cash position, and cash expected to be generated from sales of the Company's approved products, FC2, and ENTADFI, are its ability to secure equity financing or other financing alternatives will be adequate to fund planned operations of the Company for the next 12 months. To the extent the Company may need additional capital for its operations or the conditions for raising capital are favorable, the Company may access financing alternatives that may include debt financing, common stock offerings, or financing involving convertible debt or other equity-linked securities and may include financings under the Company's current effective shelf registration statement on Form S-3 (File No. 333-239493) or under a new registration statement.

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### Operating activities

Operating activities used cash of \$26.6 \$34.5 million in the nine three months ended June 30, 2022 December 31, 2022. Cash used in operating activities included net loss of \$42.8 \$36.8 million, adjustments to reconcile net loss to net cash used in operating activities totaling an increase of \$9.5 \$6.4 million and changes in operating assets and liabilities resulting in an increase a decrease of \$6.6 \$4.1 million. Adjustments to net loss primarily consisted of \$6.9 \$4.8 million of share-based compensation, and interest expense in excess of interest paid of \$1.4 \$0.7 million, and the change in fair value of derivative liabilities of \$0.7 million. The increase decrease in cash from changes in operating assets and liabilities included an increase a decrease in accounts payable of \$3.5 million and an increase in accrued expenses and other current liabilities of \$8.3 million, partially offset by an increase in accounts receivable of \$0.9 million, an increase in inventory of \$2.2 \$11.4 million and an increase in prepaid expenses and other current assets of \$1.7 \$1.1 million, partially offset by an increase in accrued expenses and other current liabilities of \$8.2 million and a decrease in accounts receivable of \$0.4 million.

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Operating activities used cash of \$14.8 \$8.7 million in the nine three months ended June 30, 2021 December 31, 2021. Cash from used in operating activities included net income loss of \$11.7 \$6.4 million, adjustments to reconcile net income loss to net cash provided by used in operating activities totaling a reduction an increase of \$17.9 million \$2.7 million and changes in operating assets and liabilities resulting in a reduction of \$8.5 \$4.9 million. Adjustments to net income loss primarily consisted of \$18.4 million related to the gain on sale of the

PREBOOST® business, \$2.9 \$1.9 million of share-based compensation, interest paid expense in excess of interest expense, paid of \$0.4 million, and \$2.9 million of deferred income taxes, partially offset by \$3.7 million of share-based compensation and \$2.0 \$0.2 million for the change in fair value of derivative liabilities. The decrease in cash from changes in operating assets and liabilities included an increase in prepaid expenses and other assets of \$9.6 \$4.1 million and an increase in accounts receivable of \$3.1 million, partially offset by an increase a decrease in accrued expenses and other current liabilities of \$2.8 million, partially offset by a decrease in accounts receivable of \$0.7 million, a decrease in inventories of \$0.7 million, and an increase in accounts payable of \$0.7 million.

### Investing activities

Net cash used in investing activities was \$0.3 million in the three months ended December 31, 2022, and consisted of capital expenditures primarily at our Malaysia location.

Net cash from investing activities was \$4.4 \$2.2 million in the nine three months ended June 30, 2022 December 31, 2021, and consisted of \$5.0 primarily attributed to \$2.5 million collected on notes receivable from the sale of the Company's PREBOOST® business, partially offset by \$0.6 \$0.3 million associated with capital expenditures primarily at our U.S. location.

Net cash from investing activities was \$14.8 million in the nine months ended June 30, 2021, primarily attributed to \$15.0 million received from the sale of the Company's PREBOOST® business.

### Financing activities

Net cash provided by financing activities in the nine three months ended June 30, 2022 December 31, 2022 was \$0.4 \$1.6 million, attributed and primarily consisted of proceeds from the Premium Finance Agreement of \$1.4 million, which were used to finance the Company's directors and officers liability insurance premium and proceeds from stock option exercises of \$0.4 \$0.3 million.

Net cash provided by financing activities in the nine three months ended June 30, 2021 December 31, 2021 was \$109.5 \$0.2 million and primarily consisted of proceeds from the underwritten public offering of the Company's common stock, net of fees and costs paid through June 30, 2021 of \$108.0 million (see discussion below) and proceeds from stock option exercises of \$1.5 \$0.2 million.

### Sources of Capital

#### Common Stock Offering

On February 22, 2021, we completed an underwritten public offering of 7,419,354 shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares, at a public offering price of \$15.50 per share. Net proceeds to the Company from this offering were \$108.0 million after deducting underwriting

discounts and commissions and costs incurred by the Company. All of the shares sold in the offering were by the Company. The offering was made pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-239493).

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### *[SWK Credit Agreement](#)*

On March 5, 2018, the Company entered into a Credit Agreement (as amended, the "Credit Agreement") with the financial institutions party thereto from time to time (the "Lenders") and SWK Funding LLC, as agent for the Lenders (the "Agent"), for a synthetic royalty financing transaction. On and subject to the terms of the Credit Agreement, the Lenders provided the Company with a term loan of \$10.0 million, which was advanced to the Company on the date of the Credit Agreement. Under the Credit Agreement, the Company is required to make quarterly payments on the term loan based on the Company's product revenue from net sales of FC2 until the earlier of receipt by the Lenders of a return premium specified in the Credit Agreement or a required payment upon termination of the Credit Agreement on March 5, 2025 or an earlier change of control of the Company or sale of the FC2 business. The Company repaid the loan and return premium specified in the Credit Agreement in August 2021, and as a result has no further obligations under the Credit Agreement. The Agent has released its security interest in Company collateral previously pledged to secure its obligations under the Credit Agreement. In connection with the Credit Agreement, Veru and the Agent also entered into a Residual Royalty Agreement, dated as of March 5, 2018 (as amended, the "Residual Royalty Agreement"), which provides for an ongoing royalty payment of 5% of product revenue from net sales of FC2, which continues after the repayment of the loan and return premium under the Credit Agreement. The Residual Royalty Agreement will terminate upon (i) a change of control or sale of the FC2 business and the payment by the Company of the amount due in connection therewith pursuant to the Residual Royalty Agreement, or (ii) mutual agreement of the parties.

The Company made total payments under the Residual Royalty Agreement of \$2.1 \$0.1 million and \$0.8 million during the **nine** three months ended **June 30, 2022** December 31, 2022 and made total payments under the Credit Agreement of \$6.4 million during the nine months ended June 30, 2021. 2021, respectively. The Company currently estimates the aggregate amount of quarterly revenue-based payments payable during the 12-month period subsequent to **June 30, 2022** December 31, 2022 will be approximately \$3.1 \$1.7 million under the Residual Royalty Agreement.

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### *[Aspire Capital Purchase Agreement](#)*

On June 26, 2020, the Company entered into a common stock purchase agreement (the "2020 Purchase Agreement") with Aspire Capital Fund, LLC (Aspire Capital) which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right, from time to time in its sole discretion during the 36-month term of the 2020 Purchase Agreement, to direct Aspire Capital to purchase up to \$23.9 million of the Company's common stock in the aggregate. Upon execution of the 2020 Purchase Agreement, the Company issued and sold to Aspire Capital under the 2020 Purchase Agreement 1,644,737 shares of common stock at a price per share of \$3.04, for an aggregate purchase price of \$5,000,000. Other than the 212,130 shares of common stock issued to Aspire Capital in consideration for entering into the 2020 Purchase Agreement and the initial sale of 1,644,737 shares of common stock, the Company has no obligation to sell any shares of common stock pursuant to the 2020 Purchase Agreement and the timing and amount of any such sales are in the Company's sole discretion subject to the conditions and terms set forth in the 2020 Purchase Agreement. The Company has not sold shares to Aspire Capital under the 2020 Purchase Agreement since June 2020. As of **June 30, 2022** December 31, 2022, the amount remaining under the 2020 Purchase Agreement was \$18.9 million, which is registered under the Company's shelf registration statement on Form S-3 (File No. 333-239493).

### *[Fair Value Measurements](#)*

As of **June 30, 2022** December 31, 2022 and **September 30, 2021** September 30, 2022, the Company's financial liabilities measured at fair value on a recurring basis, which consisted of embedded derivatives, represent the fair value of the change of control provisions provision in the Credit Agreement and Residual Royalty Agreement. See Note 8 to the financial statements included in this report for additional information.

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The fair values of these liabilities were estimated based on unobservable inputs (Level 3 measurement), which requires highly subjective judgment and assumptions. The Company previously determined the fair value of the embedded derivatives using a Monte Carlo simulation model. Since the Credit Agreement has been satisfied as of September 30, 2021, estimates the fair value of the embedded derivative within the Residual Royalty Agreement has been calculated by using a scenario-based method, whereby different scenarios are valued and probability weighted. The Company determined that with only the embedded derivative under the Residual Royalty Agreement remaining, there is no material difference between these two valuation models. The scenario-based valuation model incorporates transaction details such as the contractual terms of the instrument and assumptions including projected FC2 revenues, expected cash outflows, probability and estimated dates of a change of control, risk-free interest rates and applicable credit risk. As a result, the use of different estimates or assumptions would result in a higher or lower fair value and different amounts being recorded in the Company's financial statements. Material changes in any of these inputs could result in a significantly higher or lower fair value measurement at future reporting dates, which could have a material effect on our results of operations. See Note 3 to the financial statements included in this report for additional information.

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## Item 3. Quantitative and Qualitative Disclosures About Market Risk

The Company's exposure to market risk was discussed in the "Quantitative and Qualitative Disclosures About Market Risk" section contained in the Company's Annual Report on Form 10-K for the fiscal year ended **September 30, 2021** **September 30, 2022**. There have been no material changes to such exposures since **September 30, 2021** **September 30, 2022**.

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## Item 4. Controls and Procedures

## Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this report, the Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended). Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective. It should be noted that in designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. The Company has designed its disclosure controls and procedures to reach a level of reasonable assurance of achieving desired control objectives and, based on the evaluation described above, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective at reaching that level of reasonable assurance.

## Changes in Internal Control over Financial Reporting

There were no changes in the Company's internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the Company's most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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## PART II. OTHER INFORMATION

## Item 1. Legal Proceedings

Neither the Company nor any For a description of its subsidiaries is a party to any our material pending legal proceedings, at see Legal Proceedings in Note 12, Contingent Liabilities, to the date of filing of unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, 10-Q and incorporated herein by reference.

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## Item 1A. Risk Factors

In addition to the other information set forth in this Quarterly Report on Form 10-Q, you should carefully consider the risks and uncertainties relating to the Company's business disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended **September 30, 2021** **September 30, 2022**. There have been no material changes from the risk factors previously disclosed in Part I, Item 1A, "Risk Factors," in the Company's Annual Report on Form 10-K for the fiscal year ended **September 30, 2021**, except for the following additional risk factors relating to our development of sabizabulin as a treatment for COVID-19 viral infection. Additional risks that we do not yet know of or that we currently think are immaterial may also impair our business operations, and there is significant uncertainty regarding the COVID-19 pandemic which could affect the risk factors set forth below.

**We may be unable to obtain an emergency use authorization from the FDA to market sabizabulin as a potential treatment for COVID-19 in the United States in a timely manner, if at all.**

In response to the global outbreak of COVID-19, we have been pursuing the development of sabizabulin as a treatment for COVID-19. Our ability to commercialize sabizabulin as a treatment for COVID-19 will depend on regulatory approval in the United States and other jurisdictions. In the United States, we initially plan to use the FDA's Emergency Use Authorization ("EUA") process, and on June 7, 2022, the Company submitted a request for an EUA. EUA is a form of temporary marketing authorization that the FDA may grant to an investigational drug at times when the Secretary of Health and Human Services has declared a public health emergency to exist. This declaration was made by the Secretary of Health and Human Services in March 2020 in relation to the COVID-19 pandemic. In order to grant an EUA, the FDA must determine that an investigational drug is safe and may be effective in treating the disease that is the subject of the public health emergency. Although the EUA process is designed to enable more expeditious marketing of a drug in response to a public health emergency, FDA review of an EUA application may take longer than expected and may result in the FDA requesting additional data or other information that may have the effect of delaying the EUA, and any agreements or positions taken by the FDA in a pre-EUA meeting does not bind the FDA or prevent it from later taking a different position, asking for more data, or delaying or denying the application. The FDA may decline to grant an EUA if it concludes that an investigational drug is not safe or effective. If any such issues arise in connection with our submission of an EUA for sabizabulin, our ability to market sabizabulin as a COVID-19 treatment may be delayed or dependent on a more time-consuming regulatory approval process, which may have a material adverse effect on our business. If we are granted an EUA by the FDA for sabizabulin, we would be able to distribute sabizabulin under the conditions set forth in the EUA prior to FDA approval. Furthermore, the FDA may revoke (or refuse to grant) an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, and we cannot predict how long, if ever, an EUA would remain in place. Such revocation could adversely impact our business in a variety of ways, including if sabizabulin is not yet approved by the FDA and if we and our manufacturing partners have invested in the supply chain to provide sabizabulin under an EUA.

***We may be unable to obtain emergency authorizations or approvals from regulatory authorities in foreign countries to market sabizabulin as a potential treatment for COVID-19 in a timely manner, if at all.***

Similar to the regulatory challenges we face for an EUA or approval of sabizabulin for the treatment of COVID-19 in the United States, we will not be able to market sabizabulin for the treatment of COVID-19 in any foreign jurisdiction without an applicable authorization or approval in any such foreign jurisdiction. We have never received any such authorization or approval for any of our drug candidates from any foreign regulatory authority and, even if such an authorization or approval is granted, we have no experience marketing a drug outside the United States. Like any EUA or approval in the United States, any authorization or approval outside the United States may be subject to various conditions required by any such foreign regulatory authority. There can be no assurances of the timing of receipt of any such foreign authorization or approval or whether we will receive any such foreign authorization or approval at all and, if we do receive any such authorization or approval, whether we will be able to market sabizabulin on favorable economic terms.

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***We lack experience in scaling-up and commercializing a drug product.***

We are working toward the large-scale technical development, manufacturing scale-up and larger scale deployment of sabizabulin as a COVID-19 treatment. To support the scale-up, we have expended and will need to continue to expend significant resources and capital. In connection with this process, we may seek to enter into a collaboration or other arrangement with a larger organization, although we may be unable to enter into such arrangements on favorable terms, or at all, or may decide to proceed with development and commercialization on our own. In that case, we will need to expend significant resources to commercialize sabizabulin, which may require additional financial resources. As part of our efforts, we intend to apply for an advanced purchase agreement from the U.S. government and governments outside the U.S. There can be no assurances that any such advanced purchase agreements will be executed. The government from which an advanced purchase agreement is obtained may also impose restrictions on or mandate input as to our conduct of manufacturing activities or distribution activities, which may cause delays in the event of disagreement.

In addition, since the path to licensure or emergency approval of any COVID-19 treatment remains uncertain, we may have a widely used drug in circulation in the United States or another country prior to our receipt of marketing approval. Unexpected safety issues, including any that we have not yet observed in our clinical trials for sabizabulin, could lead to significant reputational damage for us and our drug development program going forward and other issues, including delays in our other programs, the need for re-design of our clinical trials and the need for significant additional financial resources.

***If we are unable to manufacture sabizabulin as a COVID-19 treatment in sufficient quantities, at sufficient yields or are unable to obtain regulatory approvals for a manufacturing facility for sabizabulin, we may experience delays in product development, regulatory approval and commercial distribution.***

Commercialization of sabizabulin as a COVID-19 treatment will require access to facilities to manufacture sabizabulin at sufficient yields and at commercial-scale. We have no experience in manufacturing any of our drug candidates in the volumes that would be necessary to support commercial sales. Efforts to establish these capabilities may not meet initial expectations as to scheduling, scale-up, reproducibility, yield, purity, cost, potency or quality. In addition, other companies, many with substantial resources, may compete with us for access to materials needed to manufacture sabizabulin.

Manufacturing sabizabulin as a COVID-19 treatment will involve a complicated process with which we have limited experience. We are dependent on third-party organizations to conduct our manufacturing activities. If third-party manufacturing organizations are unable to manufacture sabizabulin in commercial quantities and at sufficient yields, then we will need to identify and reach supply arrangements with additional third parties. Third-party manufacturers must also be inspected by the FDA as part of the FDA's review of our marketing application. Sabizabulin may be in competition with other products for access to these facilities and may be subject to delays in manufacturing if third parties give other products higher priority. We may not be able to enter into any necessary additional third-party manufacturing arrangements on acceptable terms, or on a timely basis. In addition, we have to enter into technical transfer agreements and share our know-how with the third-party manufacturers, which can be time-consuming and may result in delays. Any delay in the manufacture or delivery of sabizabulin could adversely affect our ability to sell sabizabulin as a COVID-19 treatment, if approved.

Our reliance on third-party manufacturers may adversely affect our operations or result in unforeseen delays or other problems beyond our control. Because of contractual restraints and the limited number of third-party manufacturers with the expertise, required regulatory approvals and facilities to manufacture sabizabulin on a commercial scale,

replacement of a manufacturer may be expensive and time-consuming and may cause interruptions in the production of sabizabulin. A third-party manufacturer may also encounter difficulties in production. These problems may include:

- difficulties with production costs, scale up and yields;
- availability of raw materials and supplies;
- quality control and assurance;
- shortages of qualified personnel;
- compliance with strictly enforced federal, state and foreign regulations that vary in each country where products might be sold; and
- lack of capital funding.

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As a result, any delay or interruption could have a material adverse effect on our business, financial condition, or results of operations.

#### **We may face competition in connection with sabizabulin for a COVID-19 treatment.**

Another party may be successful in producing a more efficacious treatment for COVID-19 which may also lead to the diversion of governmental and quasi-governmental funding away from us and toward other companies. In particular, given the widespread media attention on the current COVID-19 pandemic, there are efforts by public and private entities to develop COVID-19 treatments. Those other entities may develop COVID-19 treatments that, as compared to sabizabulin, are more effective, become the standard of care, have broader market acceptance, are safer or have fewer or less severe side effects, are more convenient, are developed at a lower cost or earlier, or may be more successfully commercialized. Many of these other organizations are much larger than we are and have access to larger pools of capital and broader manufacturing infrastructure. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their vaccine candidates. Our business could be materially and adversely affected if competitors develop and commercialize one or more COVID-19 treatments before we can complete development and seek approval for sabizabulin.

#### **Our ability to produce a treatment for the COVID-19 virus may be curtailed by government actions or interventions, which may be more likely during a global health crisis such as COVID-19.**

Given the significant global impact of the COVID-19 pandemic, it is possible that one or more government entities may take actions that directly or indirectly have the effect of diminishing some of our rights or opportunities with respect to sabizabulin and the economic value of a COVID-19 treatment to us could be limited. Governments and other health authorities may also focus on vaccines rather than treatment options such as sabizabulin in addressing the COVID-19 pandemic, which may reduce funding and other market opportunities for sabizabulin. We also intend to seek to enter into contracts with the U.S. government and other health authorities to supply sabizabulin, which will depend on spending and political priorities, the availability of alternative treatment options, and the continuation of the COVID-19 as a public health emergency. Government entities may also impose restrictions or limitations on our third-party service providers and may require us to obtain alternative sources for sabizabulin. If we are unable to timely enter into alternative arrangements, or if such alternative arrangements are not available on satisfactory terms, we will experience delays in the development or production of our sabizabulin, increased expenses, and delays in potential distribution or commercialization of our vaccine candidates, when and if approved.

#### **We may need to seek and secure significant funding through financings or from other sources to effectively commercialize sabizabulin as a treatment for COVID-19.**

We are currently advancing our pipeline of prostate and breast cancer drug candidates and are conducting multiple clinical studies. Discovering development candidates and developing investigational medicines is expensive, and we expect to continue to spend substantial amounts to (i) perform basic research, perform preclinical studies, and conduct clinical trials of our current and future programs, (ii) continue to develop and expand our platform and infrastructure and supply preclinical studies and clinical trials with appropriate grade materials (including cGMP materials), (iii) seek regulatory approvals for our investigational medicines, and (iv) launch and commercialize any products for which we receive regulatory approval, including building our own commercial sales, marketing, and distribution organization. Furthermore, our ongoing work on sabizabulin will require significant additional investment during 2022 and beyond.

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As of June 30, 2022, we had approximately \$100.6 million in cash and cash equivalents. We expect that our existing cash and cash equivalents will be sufficient to fund our current operations through at least the next twelve months. However, our operating plan may change as a result of many factors currently unknown to us, including with respect to our development, manufacturing and commercialization of sabizabulin for COVID-19 and availability and conditions of advanced purchase agreements, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings, structured financings, government or other third-party funding, sales of assets, marketing and distribution arrangements, other collaborations and licensing arrangements, or a combination of these approaches. Even if we believe we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Our spending will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with discovery of development candidates and development of our investigational medicines are highly uncertain, we are unable to estimate the actual funds we will require for development, marketing, and commercialization activities.

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### Item 6. Exhibits

#### Exhibit

Number	Description
2.1	<a href="#">Asset Purchase Agreement, dated as of December 8, 2020, between the Company and Roman Health Ventures Inc. (incorporated by reference to Exhibit 2.2 to the Company's Form 10-K (File No. 1-13602) filed with the SEC on December 10, 2020).</a>
3.1	<a href="#">Amended and Restated Articles of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Form SB-2 Registration Statement (File No. 333-89273) filed with the SEC on October 19, 1999).</a>
3.2	<a href="#">Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 27,000,000 shares (incorporated by reference to Exhibit 3.2 to the Company's Form SB-2 Registration Statement (File No. 333-46314) filed with the SEC on September 21, 2000).</a>
3.3	<a href="#">Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 35,500,000 shares (incorporated by reference to Exhibit 3.3 to the Company's Form SB-2 Registration Statement (File No. 333-99285) filed with the SEC on September 6, 2002).</a>
3.4	<a href="#">Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 38,500,000 shares (incorporated by reference to Exhibit 3.4 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 15, 2003).</a>
3.5	<a href="#">Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 3 (incorporated by reference to Exhibit 3.5 to the Company's Form 10-QSB (File No. 1-13602) filed with the SEC on May 17, 2004).</a>
3.6	<a href="#">Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company designating the terms and preferences for the Class A Preferred Stock – Series 4 (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on November 2, 2016).</a>
3.7	<a href="#">Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company changing the corporate name to Veru Inc. and increasing the number of authorized shares of common stock to 77,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on August 1, 2017).</a>
3.8	<a href="#">Articles of Amendment to the Amended and Restated Articles of Incorporation of the Company increasing the number of authorized shares of common stock to 154,000,000 shares (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on March 29, 2019).</a>
3.9	<a href="#">Amended and Restated By-Laws (incorporated by reference to Exhibit 3.1 to the Company's Form 8-K (File No. 1-13602) filed with the SEC on May 4, 2018).</a>
4.1	Amended and Restated Articles of Incorporation, as amended (same as Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> , <a href="#">3.3</a> , <a href="#">3.4</a> , <a href="#">3.5</a> , <a href="#">3.6</a> , <a href="#">3.7</a> and <a href="#">3.8</a> ).
4.2	<a href="#">Articles II, VII and XI of the Amended and Restated By-Laws (included in Exhibit 3.9).</a>
10.1	<a href="#">Veru Inc. 2022 Employment Inducement Equity Incentive Plan. *</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *</a>

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31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. *</a>
32.1	<a href="#">Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350 (Section 906 of the Sarbanes-Oxley Act of 2002). *, **</a>

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101	The following materials from the Company's Quarterly Report on Form 10-Q for the quarter ended <a href="#">June 30, 2022</a> <a href="#">December 31, 2022</a> , formatted in iXBRL (Inline Extensible Business Reporting Language): (1) the Unaudited Condensed Consolidated Balance Sheets, (2) the Unaudited Condensed Consolidated Statements of Operations, (3) the Unaudited Condensed Consolidated Statements of Stockholders' Equity, (4) the Unaudited Condensed Consolidated Statements of Cash Flows and (5) the Notes to the Unaudited Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted as iXBRL and contained in Exhibit 101).

\* Filed herewith

\*\* This certification is not "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

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## SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**VERU INC.**

DATE: August 11, 2022 February 9, 2023

/s/ Mitchell S. Steiner

Mitchell S. Steiner

Chairman, Chief Executive Officer and President

DATE: August 11, 2022 February 9, 2023

/s/ Michele Greco

Michele Greco

Chief Financial Officer and Chief Administrative Officer

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**Exhibit 10.1**

**VERU INC.**

**2022 EMPLOYMENT INDUCEMENT EQUITY INCENTIVE PLAN**

**VERU INC.**

**2022 EMPLOYMENT INDUCEMENT EQUITY INCENTIVE PLAN**

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**VERU INC.**

**2022 EMPLOYMENT INDUCEMENT EQUITY INCENTIVE PLAN**

**1. Purpose.** The purpose of this VERU INC. 2022 EMPLOYMENT INDUCEMENT EQUITY INCENTIVE PLAN (the "Plan") is to assist Veru Inc. (the "Company") and its Related Entities (as hereinafter defined) in attracting, motivating, retaining and rewarding Eligible Persons who provide services to the Company or its Related Entities by enabling such persons to acquire or increase a proprietary interest in the Company in order to strengthen the mutuality of interests between such persons and the Company's stockholders, and providing such persons with performance incentives to expend their maximum efforts in the creation of stockholder value.

**2. Definitions.** For purposes of the Plan, the following terms shall be defined as set forth below, in addition to such terms defined in Section 1 hereof and elsewhere herein.

**(a) "Award"** means any Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award, Share granted as a bonus or in lieu of another Award, Dividend Equivalent, Other Stock-Based Award or Performance Award, together with any other right or interest relating to Shares or other property (including cash), granted to a Participant under the Plan.

**(b) "Award Agreement"** means any written agreement, contract or other instrument or document evidencing any Award granted by the Committee hereunder.

(c) **"Beneficiary"** means the person, persons, trust or trusts that have been designated by a Participant in his or her most recent written beneficiary designation filed with the Committee to receive the benefits specified under the Plan upon such Participant's death or to which Awards or other rights are transferred if and to the extent permitted under Section 9(b) hereof. If, upon a Participant's death, there is no designated Beneficiary or surviving designated Beneficiary, then the term Beneficiary means the person, persons, trust or trusts entitled by will or the laws of descent and distribution to receive such benefits.

(d) **"Beneficial Owner" and "Beneficial Ownership"** shall have the meaning ascribed to such term in Rule 13d-3 under the Exchange Act and any successor to such Rule.

(e) **"Board"** means the Company's Board of Directors.

(f) **"Cause"** shall, with respect to any Participant, have the meaning specified in the Award Agreement. In the absence of any definition in the Award Agreement, "Cause" shall have the equivalent meaning or the same meaning as "cause" or "for cause" set forth in any employment or other agreement for the performance of services between the Participant and the Company or a Related Entity or, in the absence of any such agreement or any such definition in such agreement, such term shall mean (i)the failure by the Participant to perform, in a reasonable manner, his or her duties as assigned by the Company or a Related Entity, (ii)any violation or breach by the Participant of his or her employment, consulting or other similar agreement with the Company or a Related Entity, if any, (iii) any violation or breach by the Participant of any non-competition, non-solicitation, non-disclosure and/or other similar agreement with the Company or a Related Entity, (iv) any act by the Participant of dishonesty or bad faith with respect to the Company or a Related Entity, (v) use of alcohol, drugs or other similar substances in a manner that adversely affects the Participant's work performance, or (vi) the commission by the Participant of any act, misdemeanor or crime reflecting unfavorably upon the Participant or the Company or any Related Entity. The good faith determination by the Committee of whether the Participant's Continuous Service was terminated by the Company for "Cause" shall be final and binding for all purposes hereunder.

(g) **"Change of Control"** means a Change of Control as defined in Section 8(b) of the Plan.

(h) **"Code"** means the Internal Revenue Code of 1986, as amended from time to time, including regulations thereunder and successor provisions and regulations thereto.

(i) **"Committee"** means the Compensation Committee of the Board. The Committee shall consist of at least two directors, each of whom shall be (i)a "non-employee director" within the meaning of Rule 16b-3 (or any successor rule) under the Exchange Act, unless administration of the Plan by "non-employee directors" is not then required in order for exemptions under Rule 16b-3 to apply to transactions under the Plan and (ii)"Independent."

(j) **"Consultant"** means any consultant or advisor who is a natural person and who provides services to the Company or any Subsidiary, so long as such person (i)renders bona fide services that are not in connection with the offer and sale of the Company's securities in a capital-raising transaction, (ii)does not directly or indirectly promote or maintain a market for the Company's securities and (iii) otherwise qualifies as a defacto employee or consultant under the applicable rules of the Securities and Exchange Commission for registration of shares of stock on a Form S-8 registration statement.

(k) "**Continuous Service**" means the uninterrupted provision of services to the Company or any Related Entity in any capacity of Employee, Director, Consultant or other service provider. Continuous Service shall not be considered to be interrupted in the case of (i) any approved leave of absence, (ii) transfers among the Company, any Related Entities or any successor entities, in any capacity of Employee, Director, Consultant or other service provider, or (iii) any change in status as long as the individual remains in the service of the Company or a Related Entity in any capacity of Employee, Director, Consultant or other service provider (except as otherwise provided in the Award Agreement). An approved leave of absence shall include sick leave, military leave or any other authorized personal leave.

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(l) "**Director**" means a member of the Board or the board of directors of any Related Entity.

(m) "**Disability**" means a permanent and total disability, (within the meaning of Section 22(e) of the Code), as determined by a medical doctor satisfactory to the Committee.

(n) "**Dividend Equivalent**" means a right, granted to a Participant under Section 6(g) hereof, to receive cash, Shares, other Awards or other property equal in value to dividends paid with respect to a specified number of Shares.

(o) "**Effective Date**" means the effective date of the Plan, which shall be June 16, 2022.

(p) "**Eligible Person**" means any prospective Employee who has not previously been an Employee or Director of the Company or a Subsidiary, or who is commencing employment with the Company or a Subsidiary following a bona fide period of non-employment by the Company or a Subsidiary, if he or she is granted an Award in connection with his or her commencement of employment with the Company or a Subsidiary and such grant is an inducement material to his or her entering into employment with the Company or a Subsidiary (within the meaning of Nasdaq Stock Market Rule 5635(c)(4) or any successor rule, if the Company's securities are traded on the Nasdaq Stock Market, and/or the applicable requirements of any other established stock exchange on which the Company's securities are traded, as applicable, as such rules and requirements may be amended from time to time). The Committee may in its discretion adopt procedures from time to time to ensure that a prospective Employee is eligible to participate in the Plan prior to the granting of any Awards to such individual under the Plan (including without limitation a requirement that each such prospective Employee certify to the Company prior to the receipt of an Award under the Plan that he or she has not been previously employed by the Company or a Subsidiary, or if previously employed, has had a bona fide period of non-employment, and that the grant of Awards under the Plan is an inducement material to his or her agreement to enter into employment with the Company or a Subsidiary).

(q) "**Employee**" means any person who is an employee of the Company or any Subsidiary.

(r) "**Exchange Act**" means the Securities Exchange Act of 1934, as amended from time to time, including rules thereunder and successor provisions and rules thereto.

(s) "**Fair Market Value**" means, as of any date, the value of a Share determined as follows:

(i) if a Share is listed on any national securities exchange, including, without limitation, the NASDAQ Stock Market, its Fair Market Value shall be the closing sales price for such stock (or the closing bid, if no sales were reported) as quoted on such exchange for the day of determination, as reported in The Wall Street Journal or such other source as the Committee deems reliable;

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(ii) if a Share is regularly quoted by a recognized securities dealer but selling prices are not reported, the Fair Market Value of a Share shall be the mean between the high bid and low asked prices for such Share for the day of determination, as reported in The Wall Street Journal or such other source as the Committee deems reliable; or

(iii) in the absence of an established market for a Share, the Fair Market Value shall be determined in good faith by the Committee.

(t) "**Independent**", when referring to either the Board or members of the Committee, shall have the same meaning as used in the rules of the Listing Market.

(u) "**Incumbent Board**" means the Incumbent Board as defined in Section 8(b)(ii) hereof.

(v) "**Listing Market**" means the national securities exchange on which any securities of the Company are listed for trading, and if not listed for trading, by the rules of the Nasdaq Stock Market.

(w) "**Non-Qualified Stock Option**" means a right granted to a Participant under Section 6(b) hereof, to purchase Shares or other Awards at a specified price during specified time periods. Options granted under the Plan do not qualify as "incentive stock options" within the meaning of Section 422 of the Code.

(x) "**Optionee**" means a person to whom a Non-Qualified Stock Option is granted under this Plan or any person who succeeds to the rights of such person under this Plan.

(y) "**Other Stock-Based Awards**" means Awards granted to a Participant under Section 6(i) hereof.

(z) "**Participant**" means an Eligible Person who has been granted an Award under the Plan which remains outstanding, including a person who was an Eligible Person at the time of grant but is no longer an Eligible Person.

(aa) "**Performance Award**" means any Award of Performance Shares or Performance Units granted pursuant to Section 6(h) hereof.

(bb) "**Performance Period**" means that period established by the Committee at the time any Award is granted or at any time thereafter during which any performance goals specified by the Committee with respect to such Award are to be measured.

(cc) "**Performance Share**" means any grant pursuant to Section 6(h) hereof of a unit valued by reference to a designated number of Shares, which value may be paid to the Participant by delivery of such property as the Committee shall determine, including cash, Shares, other property or any combination thereof, upon achievement of such performance goals during the Performance Period as the Committee shall establish at the time of such grant or thereafter.

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(dd) "**Performance Unit**" means any grant pursuant to Section 6(h) hereof of a unit valued by reference to a designated amount of property (including cash) other than Shares, which value may be paid to the Participant by delivery of such property as the Committee shall determine, including cash, Shares, other property or any combination thereof, upon achievement of such performance goals during the Performance Period as the Committee shall establish at the time of such grant or thereafter.

(ee) "**Person**" shall have the meaning ascribed to such term in Section 3(a)(9) of the Exchange Act and used in Sections 13(d) and 14(d) thereof, and shall include a "group" as defined in Section 13(d) thereof.

(ff) **"Related Entity"** means any Subsidiary, and any business, corporation, partnership, limited liability company or other entity designated by the Board, in which the Company or a Subsidiary holds a substantial ownership interest, directly or indirectly.

(gg) **"Restricted Stock"** means any Share issued with such risks of forfeiture and other restrictions as the Committee, in its sole discretion, may impose (including any restriction on the right to vote such Share and the right to receive any dividends), which restrictions may lapse separately or in combination at such time or times, in installments or otherwise, as the Committee may deem appropriate.

(hh) **"Restricted Stock Award"** means an Award granted to a Participant under Section 6(d) hereof.

(ii) **"Restricted Stock Unit"** means a right to receive Shares, including Restricted Stock, cash measured based upon the value of Shares or a combination thereof, at the end of a specified deferral period.

(jj) **"Restricted Stock Unit Award"** means an Award of Restricted Stock Unit granted to a Participant under Section 6(e) hereof.

(kk) **"Restriction Period"** means the period of time specified by the Committee that Restricted Stock Awards shall be subject to such restrictions on transferability, risk of forfeiture and other restrictions, if any, as the Committee may impose.

(ll) **"Rule 16b-3"** means Rule 16b-3, as from time to time in effect and applicable to the Plan and Participants, promulgated by the Securities and Exchange Commission under Section 16 of the Exchange Act.

(mm) **"Shares"** means the shares of common stock of the Company and such other securities as may be substituted (or resubstituted) for Shares pursuant to Section 9(c) hereof.

(nn) **"Stock Appreciation Right"** means a right granted to a Participant under Section 6(c) hereof.

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(oo) **"Subsidiary"** means any corporation or other entity in which the Company has a direct or indirect ownership interest of 50% or more of the total combined voting power of the then outstanding securities or interests of such corporation or other entity entitled to vote generally in the election of directors or in which the company has the right to receive 50% or more of the distribution of profits or 50% or more of the assets, as that term is defined in Rule 405 of under the Securities Act of 1933, controlled by the Company directly, or indirectly, through one or more intermediaries.

(pp) **"Substitute Awards"** means Awards granted or Shares issued by the Company in assumption of, or in substitution or exchange for, Awards previously granted, or the right or obligation to make future Awards, by a company (i) acquired by the Company or any Related Entity; (ii) which becomes a Related Entity after the date hereof or (iii) with which the Company or any Related Entity combines.

### 3. Administration.

(a) **Authority of the Committee.** The Plan shall be administered by the Committee; provided, however, that except as otherwise expressly provided in this Plan, the Board may exercise any power or authority granted to the Committee under this Plan and, in that case, references herein shall be deemed to include references to the Board. The Committee shall have full and final authority, subject to and consistent with the provisions of the Plan, to select Eligible Persons to become Participants; grant Awards; determine the type, number and other terms and conditions of, and all other matters relating to, Awards; prescribe Award Agreements (which need not be identical for each Participant) and rules and regulations for the administration of the Plan; construe and interpret the Plan and Award Agreements and correct defects, supply omissions or reconcile inconsistencies therein; and to make all other decisions and determinations as the Committee may deem necessary or advisable for the administration of the Plan. In exercising any discretion granted to the Committee under the Plan or pursuant to any Award, the Committee shall not be required to follow past practices, act in a manner consistent with past practices, or treat any Eligible Person or Participant in a manner consistent with the treatment of any other Eligible Persons or Participants. Decisions of the Committee shall be final, conclusive and binding on all persons or entities, including the Company, any Subsidiary or any Participant or Beneficiary, or any transferee under Section 9(b) hereof or any other person or entity claiming rights from or through any of the foregoing persons or entities.

(b) **Manner of Exercise of Committee Authority.**

(i) The Committee, and not the Board, shall exercise sole and exclusive discretion on any matter relating to a Participant then subject to Section 16 of the Exchange Act with respect to the Company to the extent necessary in order that transactions by such Participant shall be exempt under Rule 16b-3 under the Exchange Act.

(ii) Any action of the Committee shall be final, conclusive and binding on all Persons, including the Company, its Related Entities, Eligible Persons, Participants, Beneficiaries, transferees under Section 9(b) hereof or other persons claiming rights from or through a Participant, and stockholders. The express grant of any specific power to the Committee, and the taking of any action by the Committee, shall not be construed as limiting any power or authority of the Committee. The Committee may delegate to members of the Board, or officers or managers of the Company or any Related Entity, or committee thereof, the authority subject to such terms and conditions as the Committee shall determine, to perform such functions, including administrative functions, as the Committee may determine to the extent that such delegation will not result in the loss of an exemption under Rule 16b-3(d)(1) of the Exchange Act for Awards granted to Participants subject to Section 16 of the Exchange Act in respect of the Company. The Committee may appoint agents to assist it in administering the Plan.

(c) **Limitation of Liability.** The Committee and the Board and each member thereof shall be entitled to, in good faith, rely or act upon any report or other information furnished to him or her by any officer or Employee, the Company's independent auditors, Consultants or any other agents assisting in the administration of the Plan. Members of the Committee and the Board, and any officer or Employee acting at the direction or on behalf of the Committee or the Board, shall not be personally liable for any action or determination taken or made in good faith with respect to the Plan, and shall, to the extent permitted by law, be fully indemnified and protected by the Company with respect to any such action or determination.

(d) **Actions Required Upon Grant of Award.** Following the issuance of any Award under the Plan, the Company shall, in accordance with the listing requirements of the Listing Market, (a) promptly issue a press release disclosing the material terms of the grant, including the recipient(s) of the grant and the number of shares involved (and if the disclosure relates to an Award to an executive officer or the Award was individually negotiated, then the disclosure must include the identity of the recipient), and (b) notify the Listing Market of such grant no later than the earlier to occur of (i) five calendar days after entering into the agreement to issue the Award or (ii) the date of the public announcement of the Award.

4. **Shares Subject to Plan.**

(a) **Limitation on Overall Number of Shares Available for Delivery under the Plan.** Subject to adjustment as provided in Section 9(c) hereof, the total number of Shares reserved and available for delivery under the Plan shall be 4,000,000. Any Shares delivered under the Plan may consist, in whole or in part, of authorized and unissued shares or treasury shares.

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(b) **Application of Limitation to Grants of Awards.** No Award may be granted if the number of Shares to be delivered in connection with such an Award exceeds the number of Shares remaining available for delivery under the Plan, minus the number of Shares deliverable in settlement of or relating to then outstanding Awards. The Committee may adopt reasonable counting procedures to ensure appropriate counting, avoid double counting (as, for example, in the case of tandem or substitute awards) and make adjustments if the number of Shares actually delivered differs from the number of Shares previously counted in connection with an Award.

(c) **Availability of Shares Not Delivered under Awards and Adjustments to Limits.**

(i) If any Shares subject to an Award, on or after the Effective Date, are forfeited, expire or otherwise terminate without issuance of such Shares, or any Award, on or after the Effective Date, is settled for cash, or otherwise does not result in the issuance of all or a portion of the Shares subject to such Award, the Shares to which those Awards were subject shall, to the extent of such forfeiture, expiration, termination, non-issuance or cash settlement, again be available for delivery with respect to Awards under the Plan, subject to Section 4(c)(iv) below.

(ii) Substitute Awards shall not reduce the Shares authorized for delivery under the Plan or authorized for delivery to a Participant in any period.

(iii) Any Share that again becomes available for delivery pursuant to this Section 4(c) shall be added back as one Share.

(iv) Notwithstanding anything to the contrary contained herein, Shares subject to an Award under the Plan shall not again be made available for issuance or delivery under the Plan if such Shares are (A) Shares tendered in payment of a Non-Qualified Stock Option, (B) Shares delivered or withheld by the Company to satisfy any tax withholding obligation or (C) Shares covered by a stock-settled Stock Appreciation Right or other Awards that were not issued upon the settlement of the Award.

5. **Eligibility.** Awards may be granted under the Plan only to Eligible Persons.

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6. **Specific Terms of Awards.**

(a) **Committee Authority.** Awards may be granted on the terms and conditions set forth in this Section 6. In addition, the Committee may impose on any Award, or the exercise thereof, at the date of grant or thereafter (subject to Section 9(e)), such additional terms and conditions, not inconsistent with the provisions of the Plan, as the Committee shall determine, including terms requiring forfeiture of Awards in the event of termination of the Participant's Continuous Service and terms permitting a Participant to make elections relating to his or her Award. Except as otherwise expressly provided herein, the Committee shall retain full power and discretion to accelerate, waive or modify, at any time, any term or condition of an Award that is not mandatory under the Plan. Except in cases in which the Committee is authorized to require other forms of consideration under the Plan, or to the extent other forms of consideration must be paid to satisfy the requirements of applicable law, no consideration other than services may be required for the grant (as opposed to the exercise) of any Award.

(b) **Non-Qualified Stock Options.** The Committee is authorized to grant Non-Qualified Stock Options to any Eligible Person on the following terms and conditions:

(i) **Exercise Price.** Other than in connection with Substitute Awards, the exercise price per Share purchasable under a Non-Qualified Stock Option shall be determined by the Committee, provided that such exercise price shall not be less than 100% of the Fair Market Value of a Share on the date of grant of the Non-Qualified Stock Option and shall not, in any event, be less than the par value of a Share on the date of grant of the Non-Qualified Stock Option. The Committee shall not be permitted to (A) lower the exercise price per Share of a Non-Qualified Stock Option after it is granted, (B) cancel a Non-Qualified Stock Option when the exercise price per Share exceeds the Fair Market Value of the underlying Shares in exchange for cash or another Award (other than in connection with Substitute Awards), (C) cancel an outstanding Non-Qualified Stock Option in exchange for a Non-Qualified Stock Option with an exercise price that is less than the exercise price of the original Non-Qualified Stock Options or (D) take any other action with respect to a Non-Qualified Stock Option that may be treated as a repricing pursuant to the applicable rules of the Listing Market, without approval of the Company's stockholders.

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(ii) **Time and Method of Exercise.** The Committee shall determine the time or times at which or the circumstances under which a Non-Qualified Stock Option may be exercised in whole or in part (including based on achievement of performance goals and/or future service requirements), the method by which notice of exercise is to be given and the form of exercise notice to be used, the time or times at which Non-Qualified Stock Options shall cease to be or become exercisable following termination of Continuous Service or upon other conditions, the methods by which the exercise price may be paid or deemed to be paid (including in the discretion of the Committee a cashless exercise procedure), the form of such payment, including, without limitation, cash, Shares (including without limitation the withholding of Shares otherwise deliverable pursuant to the Award), other Awards or awards granted under other plans of the Company or a Related Entity, or other property (including notes, or other contractual obligations of Participants to make payment on a deferred basis provided that such deferred payments are not in violation of Section 13(k) of the Exchange Act, any rule or regulation adopted thereunder or any other applicable law), and the methods by or forms in which Shares will be delivered or deemed to be delivered to Participants.

(iii) **Form of Settlement.** The Committee may, in its sole discretion, provide that the Shares to be issued upon exercise of a Non-Qualified Stock Option shall be in the form of Restricted Stock, or other similar securities.

(c) **Stock Appreciation Rights.** The Committee may grant Stock Appreciation Rights to any Eligible Person in conjunction with all or part of any Non-Qualified Stock Option granted under the Plan or at any subsequent time during the term of such Non-Qualified Stock Option (a "**Tandem Stock Appreciation Right**"), or without regard to any Non-Qualified Stock Option (a "**Freestanding Stock Appreciation Right**"), in each case upon such terms and conditions as the Committee may establish in its sole discretion, not inconsistent with the provisions of the Plan, including the following:

(i) **Right to Payment.** A Stock Appreciation Right shall confer on the Participant to whom it is granted a right to receive, upon exercise thereof, the excess of (A) the Fair Market Value of one Share on the date of exercise over (B) the grant price of the Stock Appreciation Right as determined by the Committee. The grant price of a Stock Appreciation Right shall not be less than 100% of the Fair Market Value of a Share on the date of grant. The Committee shall not be permitted to (A) lower the grant price per Share of a Stock Appreciation Right after it is granted, (B) cancel a Stock Appreciation Right when the grant price per Share exceeds the Fair Market Value of the underlying Shares in exchange for another Award (other than in connection with Substitute Awards), (C) cancel an outstanding Stock Appreciation Right in exchange for a Stock Appreciation Right with a grant price that is less than the grant price of the original Stock Appreciation Right or (D) take any other action with respect to a Stock Appreciation Right that may be treated as a repricing pursuant to the applicable rules of the Listing Market, without stockholder approval.

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(ii) **Other Terms.** The Committee shall determine the date of grant or thereafter the time or times at which and the circumstances under which a Stock Appreciation Right may be exercised in whole or in part (including based on achievement of performance goals and/or future service requirements), the time or times at which Stock Appreciation Rights shall cease to be or become exercisable following termination of Continuous Service or upon other conditions, the method of exercise, method of settlement, form of consideration payable in settlement, method by or forms in which Shares will be delivered or deemed to be delivered to Participants, whether or not a Stock Appreciation Right shall be in tandem or in combination with any other Award and any other terms and conditions of any Stock Appreciation Right.

(iii) **Tandem Stock Appreciation Rights.** Any Tandem Stock Appreciation Right may be granted at the same time as the related Non-Qualified Stock Option is granted or at any time thereafter before exercise or expiration of such Non-Qualified Stock Option. Any Tandem Stock Appreciation Right related to a Non-Qualified Stock Option may be exercised only when the related Non-Qualified Stock Option would be exercisable and the Fair Market Value of the Shares subject to the related Non-Qualified Stock Option exceeds the exercise price at which Shares can be acquired pursuant to the Non-Qualified Stock Option. In addition, if a Tandem Stock Appreciation Right exists with respect to less than the full number of Shares covered by a related Non-Qualified Stock Option, then an exercise or termination of such Non-Qualified Stock Option shall not reduce the number of Shares to which the Tandem Stock Appreciation Right applies until the number of Shares then exercisable under such Non-Qualified Stock Option equals the number of Shares to which the Tandem Stock Appreciation Right applies. Any Non-Qualified Stock Option related to a Tandem Stock Appreciation Right shall no longer be exercisable to the extent the Tandem Stock Appreciation Right has been exercised, and any Tandem Stock Appreciation Right shall no longer be exercisable to the extent the related Non-Qualified Stock Option has been exercised.

(d) **Restricted Stock Awards.** The Committee is authorized to grant Restricted Stock Awards to any Eligible Person on the following terms and conditions:

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(i) **Grant and Restrictions.** Restricted Stock Awards shall be subject to such restrictions on transferability, risk of forfeiture and other restrictions, if any, as the Committee may impose, or as otherwise provided in this Plan during the Restriction Period. The terms of any Restricted Stock Award granted under the Plan shall be set forth in a written Award Agreement which shall contain provisions determined by the Committee and not inconsistent with the Plan. The restriction may lapse separately or in combination at such times, under such circumstances (including based on achievement of performance goals and/or future service requirements), in such installments or otherwise, as the Committee may determine at the date of grant or thereafter. Except to the extent restricted under the terms of the Plan and any Award Agreement relating to a Restricted Stock Award, a Participant granted Restricted Stock shall have all of the rights of a stockholder, including the right to vote the Restricted Stock and the right to receive dividends thereon, provided that any dividends with respect to a Restricted Stock Award shall be withheld by the Company for the account of the Participant holding such Restricted Stock Award, and interest may be credited on the amount of the dividends withheld at a rate and subject to such terms as determined by the Committee. The dividends so withheld by the Company and attributable to any particular share of Restricted Stock (and earnings thereon, if applicable) shall be subject to the restrictions and a risk of forfeiture to the same extent as the share of Restricted Stock, shall be distributed to the Participant upon the release of restrictions on such share and, if such share is forfeited, the Participant shall have no right to such dividends. During the period that the Restricted Stock Award is subject to a risk of forfeiture, subject to Section 9(b) below and except as otherwise provided in the Award Agreement, the Restricted Stock may not be sold, transferred, pledged, hypothecated, margined or otherwise encumbered by the Participant or Beneficiary.

(ii) **Forfeiture.** Except as otherwise determined by the Committee, upon termination of a Participant's Continuous Service during the applicable Restriction Period, the Participant's Restricted Stock that is at that time subject to a risk of forfeiture that has not lapsed or otherwise been satisfied shall be forfeited and reacquired by the Company; provided that the Committee may provide, by resolution or other action or in any Award Agreement, or may determine in any individual case, that forfeiture conditions relating to Restricted Stock Awards shall be waived in whole or in part in the event of terminations resulting from specified causes, and the Committee may in other cases waive in whole or in part the forfeiture of Restricted Stock.

(iii) **Certificates for Stock.** Restricted Stock granted under the Plan may be evidenced in such manner as the Committee shall determine. If certificates representing Restricted Stock are registered in the name of the Participant, the Committee may require that such certificates bear an appropriate legend referring to the terms, conditions and restrictions applicable to such Restricted Stock, that the Company retain physical possession of the certificates and that the Participant deliver a stock power to the Company, endorsed in blank, relating to the Restricted Stock.

(e) **Restricted Stock Unit Award.** The Committee is authorized to grant Restricted Stock Unit Awards to any Eligible Person on the following terms and conditions:

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(i) **Award and Restrictions.** Satisfaction of a Restricted Stock Unit Award shall occur upon expiration of the deferral period specified for such Restricted Stock Unit Award by the Committee (or, if permitted by the Committee, as elected by the participant in a manner that does not violate the requirements of Section 409A of the Code). In addition, a Restricted Stock Unit Award shall be subject to such restrictions (which may include a risk of forfeiture) as the Committee may impose, if any, which restrictions may lapse at the expiration of the deferral period or at other specified times (including based on achievement of performance goals and/or future service requirements), separately or in combination, in installments or otherwise as the Committee may determine. A Restricted Stock Unit Award may be satisfied by delivery of Shares, cash equal to the Fair Market Value of the specified number of Shares covered by the Restricted Stock Units, or a combination thereof, as determined by the Committee at the date of grant or thereafter. Prior to satisfaction of a Restricted Stock Unit Award, a Restricted Stock Unit Award carries no voting or dividend or other rights associated with Share ownership. Prior to satisfaction of a Restricted Stock Unit Award, except as otherwise provided in an Award Agreement and as permitted under Section 409A of the Code, a Restricted Stock Unit Award may not be sold, transferred, pledged, hypothecated, margined or otherwise encumbered by the Participant or any Beneficiary.

(ii) **Forfeiture.** Except as otherwise determined by the Committee, upon termination of a Participant's Continuous Service during the applicable deferral period or portion thereof to which forfeiture conditions apply (as provided in the Award Agreement evidencing the Restricted Stock Unit Award), the Participant's Restricted Stock Unit Award that is at that time subject to a risk of forfeiture that has not lapsed or otherwise been satisfied shall be forfeited; provided that the Committee may provide, by resolution or other action or in any Award Agreement, or may determine in any individual case, that forfeiture conditions relating to a Restricted Stock Unit Award shall be waived in whole or in part in the event of terminations resulting from specified causes, and the Committee may in other cases waive in whole or in part the forfeiture of any Restricted Stock Unit Award.

(f) **Bonus Stock and Awards in Lieu of Obligations.** The Committee is authorized to grant Shares to any Eligible Persons as a bonus, or to grant Shares or other Awards in lieu of obligations to pay cash or deliver other property under the Plan or under other plans or compensatory arrangements, provided that, in the case of Eligible Persons subject to Section 16 of the Exchange Act, the amount of such grants remains within the discretion of the Committee to the extent necessary to ensure that acquisitions of Shares or other Awards are exempt from liability under Section 16(b) of the Exchange Act. Shares or Awards granted hereunder shall be subject to such other terms as shall be determined by the Committee.

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(g) **Dividend Equivalents.** The Committee is authorized to grant Dividend Equivalents to any Eligible Person entitling the Eligible Person to receive cash, Shares, other Awards or other property equal in value to the dividends paid with respect to a specified number of Shares. Dividend Equivalents may be awarded on a free-standing basis or in connection with another Award. Notwithstanding anything in the Plan to the contrary, any cash, Shares, other Awards or other property otherwise payable with respect to Dividend Equivalents as to any Award to the extent such Award has not vested shall be withheld by the Company for the account of the Participant holding such Award, and interest may be credited on the amount withheld at a rate and subject to such terms as determined by the Committee. The cash, Shares, other Awards or other property so withheld by the Company and attributable to any particular Award, and any interest thereon, shall be subject to the restrictions and a risk of forfeiture to the same extent as such Award, shall be distributed to the Participant upon the vesting of such Award and, if such Award is forfeited prior to its vesting, the Participant shall have no right to such cash, Shares, other Awards or other property or any interest thereon.

(h) **Performance Awards.** The Committee is authorized to grant Performance Awards to any Eligible Person payable in cash, Shares or other Awards, on terms and conditions established by the Committee. The performance criteria to be achieved during any Performance Period and the length of the Performance Period shall be determined by the Committee upon the grant of each Performance Award; provided, however, that a Performance Period shall not be shorter than twelve (12) months nor longer than five (5) years. Except as provided in Section 9 or as may be provided in an Award Agreement, Performance Awards will be distributed only after the end of the relevant Performance Period. The performance goals to be achieved for each Performance Period shall be conclusively determined by the Committee and may be based upon any criteria that the Committee, in its sole discretion, shall determine should be used for that purpose. The amount of the Award to be distributed shall be conclusively determined by the Committee. Performance Awards may be paid in a lump sum or in installments following the close of the Performance Period or, in accordance with procedures established by the Committee, on a deferred basis in a manner that does not violate the requirements of Section 409A of the Code.

(i) **Other Stock-Based Awards.** The Committee is authorized, subject to limitations under applicable law, to grant to any Eligible Person such other Awards that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, Shares, as deemed by the Committee to be consistent with the purposes of the Plan. Other Stock-Based Awards may be granted to Participants either alone or in addition to other Awards granted under the Plan, and such Other Stock-Based Awards shall also be available as a form of payment in the settlement of other Awards granted under the Plan. The Committee shall determine the terms and conditions of such Awards. Shares delivered pursuant to an Award in the nature of a purchase right granted under this Section 6(i) shall be purchased for such consideration, (including without limitation loans from the Company or a Related Entity provided that such loans are not in violation of the Sarbanes Oxley Act of 2002, as amended, or any rule or regulation adopted thereunder or any other applicable law) paid for at such times, by such methods, and in such forms, including, without limitation, cash, Shares, other Awards or other property, as the Committee shall determine.

(a) **Stand-Alone, Additional, Tandem and Substitute Awards.** Awards granted under the Plan may, in the discretion of the Committee, be granted either alone or in addition to, in tandem with or in substitution or exchange for, any other Award or any award granted under another plan of the Company, any Related Entity or any business entity to be acquired by the Company or a Related Entity, or any other right of a Participant to receive payment from the Company or any Related Entity. Subject to compliance with the Code, such additional, tandem and substitute or exchange Awards may be granted at any time. If an Award is granted in substitution or exchange for another Award or award, the Committee shall require the surrender of such other Award or award in consideration for the grant of the new Award. In addition, Awards may be granted in lieu of cash compensation, including in lieu of cash amounts payable under other plans of the Company or any Related Entity, in which the value of Shares subject to the Award is equivalent in value to the cash compensation (for example, Restricted Stock or Restricted Stock Units), or in which the exercise price, grant price or purchase price of the Award in the nature of a right that may be exercised is equal to the Fair Market Value of the underlying Shares minus the value of the cash compensation surrendered (for example, Non-Qualified Stock Options or Stock Appreciation Right granted with an exercise price or grant price "discounted" by the amount of the cash compensation surrendered), provided that any such determination to grant an Award in lieu of cash compensation must be made in a manner intended to be exempt from or comply with Section 409A of the Code.

(b) **Term of Awards.** The term of each Award shall be for such period as may be determined by the Committee provided that in no event shall the term of any Non-Qualified Stock Option or Stock Appreciation Right exceed a period of ten years.

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(c) **Form and Timing of Payment Under Awards; Deferrals.** Subject to the terms of the Plan and any applicable Award Agreement, payments to be made by the Company or a Related Entity upon the exercise of a Non-Qualified Stock Option or other Award or settlement of an Award may be made in such form as the Committee shall determine, including, without limitation, cash, Shares, other Awards or other property, and may be made in a single payment or transfer, in installments or on a deferred basis, provided that any determination to pay in installments or on a deferred basis shall be made by the Committee at the date of grant. Any installment or deferral provided for in the preceding sentence shall, however, subject to the terms of the Plan, be subject to the Company's compliance with the provisions of the Sarbanes Oxley Act of 2002, as amended, the rules and regulations adopted by the Securities and Exchange Commission thereunder, all applicable rules of the Listing Market, and in a manner intended to be exempt from or otherwise satisfy the requirements of Section 409A of the Code. Subject to Section 7(e) of this Plan, any such settlement shall be at a value determined by the Committee in its sole discretion, which, without limitation, may in the case of a Non-Qualified Stock Option or Stock Appreciation Right be limited to the amount if any by which the Fair Market Value of a Share on the settlement date exceeds the exercise or grant price. Installment or deferred payments may be required by the Committee (subject to Section 7(e) of this Plan, including the consent provisions thereof in the case of any deferral of an outstanding Award not provided for in the original Award Agreement) or permitted at the election of the Participant on terms and conditions established by the Committee. The acceleration of the settlement of any Award, and the payment of any Award in installments or on a deferred basis, shall be done all in a manner that is intended to be exempt from or otherwise satisfy the requirements of Section 409A of the Code. The Committee may, without limitation, make provision for the payment or crediting of a reasonable interest rate on installment or deferred payments or the grant or crediting of Dividend Equivalents or other amounts in respect of installment or deferred payments denominated in Shares.

(d) **Exemptions from Section 16(b) Liability.** It is the intent of the Company that the grant of any Awards to, or other transaction by, a Participant who is subject to Section 16 of the Exchange Act shall be exempt from Section 16 pursuant to an applicable exemption (except for transactions acknowledged in writing to be non-exempt by such Participant). Accordingly, if any provision of this Plan or any Award Agreement does not comply with the requirements of Rule 16b-3 then applicable to any such transaction, such provision shall be construed or deemed amended to the extent necessary to conform to the applicable requirements of Rule 16b-3 so that such Participant shall avoid liability under Section 16(b).

(e) **Code Section 409A.**

(i) The Award Agreement for any Award that the Committee reasonably determines to constitute a "nonqualified deferred compensation plan" under Section409A of the Code (a "**Section409A Plan**"), and the provisions of the Section409A Plan applicable to that Award, shall be construed in a manner consistent with the applicable requirements of Section409A of the Code, and the Committee, in its sole discretion and without the consent of any Participant, may amend any Award Agreement (and the provisions of the Plan applicable thereto) if and to the extent that the Committee determines that such amendment is necessary or appropriate to comply with the requirements of Section 409A of the Code.

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(ii) If any Award constitutes a Section409A Plan, then the Award shall be subject to the following additional requirements if, and to the extent, required to comply with Section409A of the Code.

(A) Payments under the Section409A Plan may be made only upon [i]the Participant's "separation from service", [ii]the date the Participant becomes "disabled", [iii]the Participant's death, [iv]a specified time (or pursuant to a fixed schedule) specified in the Award Agreement at the date of the deferral of such compensation, [v] a "change in the ownership or effective control of the corporation, or in the ownership of a substantial portion of the assets" of the Company or [vi] the occurrence of an "unforeseeable emergency";

(B) The time or schedule for any payment of the deferred compensation may not be accelerated, except to the extent provided in applicable Treasury Regulations or other applicable guidance issued by the Internal Revenue Service;

(C) Any elections, with respect to the deferral of such compensation or the time and form of distribution of such deferred compensation shall comply with the requirements of Section 409A(a)(4) of the Code; and

(D) In the case of any Participant who is "specified employee", a distribution on account of a "separation from service" may not be made before the date which is sixmonths after the date of the Participant's "separation from service" (or, if earlier, the date of the Participant's death).

For purposes of the foregoing, the terms in quotations shall have the same meanings as those terms have for purposes of Section409A of the Code and the Treasury Regulations promulgated thereunder, and the limitations set forth herein shall, be applied in such manner (and only to the extent) as shall be necessary to comply with any requirements of Section409A of the Code that are applicable to the Award.

(iii) Notwithstanding the foregoing, or any provision of this Plan or any Award Agreement, the Company does not make any representation to any Participant or Beneficiary that any Awards made pursuant to this Plan are exempt from, or satisfy the requirements of, Section409A of the Code, and the Company shall have no liability or other obligation to indemnify or hold harmless the Participant or any Beneficiary for any tax, additional tax, interest or penalties that the Participant or any Beneficiary may incur in the event that any provision of this Plan, or any Award Agreement, or any amendment or modification thereof, or any other action taken with respect thereto, is deemed to violate any of the requirements of Section409A of the Code.

## 8. Change of Control.

(a) **Effect of "Change of Control."** If, and only to the extent, determined by the Committee in its sole discretion and without any requirement that each Participant be treated consistently upon the occurrence of a "Change of Control," as defined in Section 8(b):

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(i) Any Non-Qualified Stock Option or Stock Appreciation Right that was not previously vested and exercisable as of the time of the Change of Control, shall become immediately vested and exercisable, subject to applicable restrictions set forth in Section 9(a) hereof.

(ii) Any restrictions, deferral of settlement and forfeiture conditions applicable to a Restricted Stock Award, Restricted Stock Unit Award or an Other Stock-Based Award subject only to future service requirements granted under the Plan shall lapse and such Awards shall be deemed fully vested as of the time of the Change of Control, except to the extent of any waiver by the Participant and subject to applicable restrictions set forth in Section 9(a) hereof.

(iii) With respect to any outstanding Award subject to achievement of performance goals and conditions under the Plan, the Committee may, in its discretion, consider such Awards to have been earned and payable based on achievement of performance goals or based upon target performance (either in full or pro-rata based on the portion of the Performance Period completed as of the Change of Control).

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Notwithstanding the foregoing or any provision in any Award Agreement to the contrary, and unless the Committee otherwise determines in a specific instance, or as is provided in any employment or other agreement between the Participant and the Company any Subsidiary, and unless the Committee otherwise determines, in a specific instance, each outstanding Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award, Performance Award or Other Stock-Based Award shall not be accelerated as described in Sections 8(a)(i), (ii) and (iii), if either (A) the Company is the surviving entity in the Change of Control and the Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award, Performance Award or Other Stock-Based Award continues to be outstanding after the Change of Control on substantially the same terms and conditions as were applicable immediately prior to the Change of Control or (B) the successor company or its parent company assumes or substitutes for the applicable Award, as determined in accordance with Section 9(c)(ii) hereof. For the purposes of this Agreement, a Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award shall be considered assumed or substituted for if, following the Change of Control, the Award confers the right to purchase or receive for each Share subject to the Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award immediately prior to the Change of Control, on substantially the same vesting and other terms and conditions as were applicable to the Award immediately prior to the Change of Control, the consideration (whether stock, cash or other securities or property) received in the transaction constituting a Change of Control by holders of Shares for each Share held on the effective date of such transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding shares); provided, however, that if such consideration received in the transaction constituting a Change of Control is not solely common stock of the successor company or its parent or subsidiary, the Committee may, with the consent of the successor company or its parent or subsidiary, provide that the consideration to be received upon the exercise or vesting of a Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award, for each Share subject thereto, will be solely common stock of the successor company or its parent or subsidiary substantially equal in fair market value to the per share consideration received by holders of Shares in the transaction constituting a Change of Control. The determination of such substantial equality of value of consideration shall be made by the Committee in its sole discretion and its determination shall be conclusive and binding.

(b) **Definition of "Change of Control."** Unless otherwise specified in any employment or other agreement for services between the Participant and the Company or any Subsidiary, or in an Award Agreement, a "Change of Control" shall mean the occurrence of any of the following:

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(i) The acquisition by any Person of Beneficial Ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of more than fifty percent (50%) of either (A) the value of then outstanding equity securities of the Company (the "**Outstanding Company Stock**") or (B) the combined voting power of the then outstanding voting securities of the Company entitled to vote generally in the election of directors (the "**Outstanding Company Voting Securities**") (the foregoing Beneficial Ownership hereinafter being referred to as a "**Controlling Interest**"); provided, however, that for purposes of this Section 8(b), the following acquisitions shall not constitute or result in a Change of Control: (v) any acquisition directly from the Company; (w) any acquisition by the Company; (x) any acquisition by any Person that as of the Effective Date owns Beneficial Ownership of a Controlling Interest; (y) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any Related Entity; or (z) any acquisition by any entity pursuant to a transaction which complies with clauses (A) or (B) of subsection (iii) below; or

(ii) During any period of two (2) consecutive years (not including any period prior to the Effective Date) individuals who constitute the Board on the Effective Date (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the Effective Date whose election, or nomination for election by the Company's stockholders, was approved by a vote of at least a majority of the directors then comprising the Incumbent Board shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or

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(iii) Consummation of (A) a reorganization, merger, statutory share exchange or consolidation or similar transaction involving (x) the Company or (y) any of its Subsidiaries, but in the case of this clause (y) only if equity securities of the Company are issued or issuable in connection with the transaction (each of the events referred to in this clause(A) being hereinafter referred to as a "**Business Reorganization**"), or (B) a sale or other disposition of all or substantially all of the assets of the Company, or the acquisition of assets or equity of another entity by the Company or any of its Subsidiaries (each an "**Asset Sale**"), in each case, unless, following such Business Reorganization or Asset Sale, (1) all or substantially all of the individuals and entities who were the Beneficial Owners, respectively, of the Outstanding Company Stock and Outstanding Company Voting Securities immediately prior to such Business Reorganization or Asset Sale beneficially own, directly or indirectly, more than fifty percent (50%) of the value of the then outstanding equity securities and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of members of the board of directors (or comparable governing body of an entity that does not have such a board), as the case may be, of the entity resulting from such Business Reorganization or Asset Sale (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company's assets either directly or through one or more subsidiaries) (the "**Continuing Entity**") in substantially the same proportions as their ownership, immediately prior to such Business Reorganization or Asset Sale, of the Outstanding Company Stock and Outstanding Company Voting Securities, as the case may be (excluding any outstanding equity or voting securities of the Continuing Entity that such Beneficial Owners hold immediately following the consummation of the Business Reorganization or Asset Sale as a result of their ownership, prior to such consummation, of equity or voting securities of any company or other entity involved in or forming part of such Business Reorganization or Asset Sale other than the Company); (2) no Person (excluding any employee benefit plan (or related trust) of the Company or any Continuing Entity, or any entity controlled by the Continuing Corporation or any Person that as of the Effective Date owns Beneficial Ownership of a Controlling Interest) beneficially owns, directly or indirectly, fifty percent (50%) or more of the value of the then outstanding equity securities of the Continuing Entity or the combined voting power of the then outstanding voting Securities of the Continuing Entity except to the extent that such ownership existed prior to the Business Reorganization or Asset Sale and (3) at least a majority of the members of the Board of Directors or other governing body of the Continuing Entity were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Business Reorganization or Asset Sale; or

(iv) Approval by the stockholders of the Company of a complete liquidation or dissolution of the Company.

## 9. General Provisions.

(a) **Compliance With Legal and Other Requirements.** The Company may, to the extent deemed necessary or advisable by the Committee, postpone the issuance or delivery of Shares or payment of other benefits under any Award until completion of such registration or qualification of such Shares or other required action under any federal or state law, rule or regulation, listing or other required action with respect to the Listing Market, or compliance with any other obligation of the Company, as the Committee may consider appropriate, and may require any Participant to make such representations, furnish such information and comply with or be subject to such other conditions as it may consider appropriate in connection with the issuance or delivery of Shares or payment of other benefits in compliance with applicable laws, rules, regulations, listing requirements or other obligations.

(b) **Limits on Transferability; Beneficiaries.** No Award or other right or interest granted under the Plan shall be pledged, hypothecated or otherwise encumbered or subject to any lien, obligation or liability of such Participant to any party, or assigned or transferred by such Participant other than by will or the laws of descent and distribution or to a Beneficiary upon the death of a Participant, and such Awards or rights that may be exercisable shall be exercised during the lifetime of the Participant only by the Participant or his or her guardian or legal representative, except that Awards and other rights may be transferred to one or more Beneficiaries or other transferees during the lifetime of the Participant, and may be exercised by such transferees in accordance with the terms of such Award, but only if and to the extent such transfers are permitted by the Committee pursuant to the express terms of an Award Agreement (subject to any terms and conditions which the Committee may impose thereon), are by gift or pursuant to a domestic relations order, and are to a "Permitted Assignee" that is a permissible transferee under the applicable rules of the Securities and Exchange Commission for registration of shares of stock on a Form S-8 registration statement. For this purpose, a Permitted Assignee shall mean (i) the Participant's spouse, children or grandchildren (including any adopted and step children or grandchildren), parents, grandparents or siblings, (ii) a trust for the benefit of one or more of the Participant or the persons referred to in clause (i), (iii) a partnership, limited liability company or corporation in which the Participant or the persons referred to in clause (i) are the only partners, members or stockholders or (iv) a foundation in which any person or entity designated in clauses (i), (ii) or (iii) above control the management of assets. A Beneficiary, transferee or other person claiming any rights under the Plan from or through any Participant shall be subject to all terms and conditions of the Plan and any Award Agreement applicable to such Participant, except as otherwise determined by the Committee, and to any additional terms and Conditions deemed necessary or appropriate by the Committee.

## (c) **Adjustments.**

(i) **Adjustments to Awards.** In the event that any extraordinary dividend or other distribution (whether in the form of cash, Shares or other property), recapitalization, forward or reverse split, reorganization, merger, consolidation, spin-off, combination, repurchase, share exchange, liquidation, dissolution or other similar corporate transaction or event affects the Shares and/or such other securities of the Company or any other issuer, then the Committee shall, in such manner as it may deem appropriate and equitable (and subject to compliance with Section 409A of the Code), substitute, exchange or adjust any or all of (A) the number and kind of Shares which may be delivered in connection with Awards granted thereafter, (B) the number and kind of Shares by which annual per person Award limitations are measured under Section 4 hereof, (C) the number and kind of Shares subject to or deliverable in respect of outstanding Awards, (D) the exercise price, grant price or purchase price relating to any Award and/or make provision for payment of cash or other property in respect of any outstanding Award and (E) any other aspect of any Award that the Committee determines to be appropriate.

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(ii) **Adjustments in Case of Certain Transactions.** In the event of any merger, consolidation or other reorganization which the Company does not survive, or in the event of any Change of Control (and subject to the provisions of Section 8 of this Plan relating to the vesting of Awards in the event of any Change of Control), any outstanding Awards may be dealt with in accordance with any of the following approaches, without the requirement of obtaining any consent or agreement of a Participant as such, as determined by the agreement effectuating the transaction or, if and to the extent not so determined, as determined by the Committee: (A) the continuation of the outstanding Awards by the Company, if the Company is a surviving entity, (B) the assumption or substitution for, as those terms are defined below, the outstanding Awards by the surviving entity or its parent or subsidiary, (C) full exercisability or vesting and accelerated expiration of the outstanding Awards or (D) settlement of the value of the outstanding Awards in cash or cash equivalents or other property followed by cancellation of such Awards (which value, in the case of Non-Qualified Stock Options or Stock Appreciation Rights, shall be measured by the amount, if any, by which the Fair Market Value of a Share exceeds the exercise or grant price of the Non-Qualified Stock Option or Stock Appreciation Right as of the effective date of the transaction). For the purposes of this Plan, a Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award shall be considered assumed or substituted for if, following the applicable transaction, the Award confers the right to purchase or receive, for each Share subject to the Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award immediately prior to the applicable transaction, or substantially the same vesting and other terms and conditions as were applicable to the Award immediately prior to the applicable transaction, the consideration (whether stock, cash or other securities or property) received in the applicable transaction by holders of Shares for each Share held on the effective date of such transaction (and if holders were offered a choice of consideration, the type of consideration chosen by the holders of a majority of the outstanding Shares); provided, however, that if such consideration received in the applicable transaction is not solely common stock of the successor company or its parent or subsidiary, the Committee may, with the consent of the successor company or its parent or subsidiary, provide that the consideration to be received upon the exercise or vesting a Non-Qualified Stock Option, Stock Appreciation Right, Restricted Stock Award, Restricted Stock Unit Award or Other Stock-Based Award, for each Share thereto, will be solely common stock of the successor company or its parent or subsidiary substantially equal in fair market value to the per share consideration received by holders of Shares in the applicable transaction. The determination of such substantial equality of value of consideration shall be made by the Committee in its sole discretion and its determination shall be conclusive and binding. The Committee shall give written notice of any proposed transaction referred to in this Section 9(c)(ii) a reasonable period of time prior to the closing date for such transaction (which notice may be given either before or after the approval of such transaction), in order that Participants may have a reasonable period of time prior to the closing date of such transaction within which to exercise any Awards that are then exercisable (including any Awards that may become exercisable upon the closing date of such transaction). A Participant may condition his or her exercise of any Awards upon the consummation of the transaction.

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(iii) **Other Adjustments.** Subject to compliance with the Code, the Committee is authorized to make adjustments in the terms and conditions of, and the criteria included in, Awards (including Awards subject to satisfaction of performance goals, or performance goals and conditions relating thereto) in recognition of unusual or nonrecurring events (including, without limitation, acquisitions and dispositions of businesses and assets) affecting the Company, any Related Entity or any business unit, or the financial statements of the Company or any Related Entity, or in response to changes in applicable laws, regulations, accounting principles, tax rates and regulations or business conditions or in view of the Committee's assessment of the business strategy of the Company, any Related Entity or business unit thereof, performance of comparable organizations, economic and business conditions, personal performance of a Participant and any other circumstances deemed relevant. Adjustments permitted hereby may include, without limitation, increasing the exercise price of Non-Qualified Stock Options and Stock Appreciation Rights, increasing performance goals or other adjustments that may be adverse to the Participant.

(d) **Award Agreements.** Each Award Agreement shall either be (i) in writing in a form approved by the Committee and executed by the Company by an officer duly authorized to act on its behalf or (ii) an electronic notice in a form approved by the Committee and recorded by the Company (or its designee) in an electronic recordkeeping system used for the purpose of tracking one or more types of Awards as the Committee may provide; in each case and if required by the Committee, the Award Agreement shall be executed or otherwise electronically accepted by the recipient of the Award in such form and manner as the Committee may require. The Committee may authorize any officer of the Company to execute any or all Award Agreements on behalf of the Company. The Award Agreement shall set forth the material terms and conditions of the Award as established by the Committee consistent with the provisions of the Plan.

(e) **Taxes.** The Company and any Related Entity are authorized to withhold from any Award granted, any payment relating to an Award under the Plan, including from a distribution of Shares, or any payroll or other payment to a Participant, amounts of withholding and other taxes due or potentially payable in connection with any transaction involving an Award, and to take such other action as the Committee may deem advisable to enable the Company or any Related Entity and Participants to satisfy obligations for the payment of withholding taxes and other tax obligations relating to any Award. This authority shall include authority to withhold or receive Shares or other property and to make cash payments in respect thereof in satisfaction of a Participant's tax obligations, either on a mandatory or elective basis in the discretion of the Committee. The amount of withholding tax paid with respect to an Award by the withholding of Shares otherwise deliverable pursuant to the Award or by delivering Shares already owned shall not exceed the minimum statutory withholding required with respect to that Award.

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(f) **Changes to the Plan and Awards.** The Board may amend, alter, suspend, discontinue or terminate the Plan, or the Committee's authority to grant Awards under the Plan, without the consent of stockholders or Participants, except that any amendment or alteration to the Plan shall be subject to the approval of the Company's stockholders not later than the annual meeting next following such Board action if such stockholder approval is required by any federal or state law or regulation (including, without limitation, Rule 16b-3) or the rules of the Listing Market, and the Board may otherwise, in its discretion, determine to submit other such changes to the Plan to stockholders for approval; provided that, except as otherwise permitted by the Plan or Award Agreement, without the consent of an affected Participant, no such Board action may materially and adversely affect the rights of such Participant under the terms of any previously granted and outstanding Award. The Committee may waive any conditions or rights under, or amend, alter, suspend, discontinue or terminate any Award theretofore granted and any Award Agreement relating thereto, except as otherwise provided in the Plan; provided that, except as otherwise permitted by the Plan or Award Agreement, without the consent of an affected Participant, no such Committee or the Board action may materially and adversely affect the rights of such Participant under terms of such Award.

(g) **Clawback of Benefits.**

(i) The Company may (A)cause the cancellation of any Award, (B)require reimbursement of any Award by a Participant or Beneficiary and (C)effect any other right of recoupment of equity or other compensation provided under this Plan or otherwise in accordance with any Company policies that currently exist or that may from time to time be adopted or modified in the future by the Company and/or applicable law (each, a "**Clawback Policy**"), provided that the following conditions are satisfied: (1)there is an accounting restatement of the Company's financial statements or results and (2)the restatement results from a noncompliance by the Company with any requirements under or related to the federal securities laws. In such an event, the clawback will be in an amount of up to the total economic gain from any stock-based grants within the five-year period preceding the restatement. By accepting an Award, a Participant is also agreeing to be bound by any existing or future Clawback Policy adopted by the Company, or any amendments that may from time to time be made to the Clawback Policy in the future by the Company in its discretion (including without limitation any Clawback Policy adopted or amended to comply with applicable laws or stock exchange requirements) and is further agreeing that all of the Participant's Award Agreements may be unilaterally amended by the Company, without the Participant's consent, to the extent that the Company, in its discretion, determines to be necessary or appropriate to comply with any Clawback Policy.

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(ii)If the Participant, without the consent of the Company, while employed by or providing services to the Company or any Subsidiary or after termination of such employment or service, violates a non-competition, non-solicitation or non-disclosure covenant or agreement or otherwise engages in activity that is in conflict with Company's Corporate Governance Guidelines, Code of Business Ethics or any other corporate governance materials specified by the SEC or exchange on which common stock of the Company is listed, then (i) any outstanding, vested or unvested, earned or unearned portion of the Award may, at the Committee's discretion, be canceled and (ii) the Committee, in its discretion, may require the Participant or other person to whom any payment has been made or Shares or other property have been transferred in connection with the Award to forfeit and pay over to the Company, on demand, all or any portion of the gain (whether or not taxable) realized upon the exercise of any Non-Qualified Stock Option or Stock Appreciation Right and the value realized (whether or not taxable) on the vesting or payment of any other Award during the time period specified in the Award Agreement or otherwise specified by the Committee.

(h) **Limitation on Rights Conferred Under Plan.** Neither the Plan nor any action taken hereunder or under any Award shall be construed as (i)giving any Eligible Person or Participant the right to continue as an Eligible Person or Participant or in the employ or service of the Company or a Related Entity, (ii)interfering in any way with the right of the Company or a Related Entity to terminate any Eligible Person's or Participant's Continuous Service at any time, (iii) giving an Eligible Person or Participant any claim to be granted any Award under the Plan or to be treated uniformly with other Participants and Employees or (iv)conferring on a Participant any of the rights of a stockholder of the Company or any Related Entity including, without limitation, any right to receive dividends or distributions, any right to vote or act by written consent, any right to attend meetings of stockholders or any right to receive any information concerning the Company's or any Related Entity's business, financial condition, results of operation or prospects, unless and until such time as the Participant is duly issued Shares on the stock books of the Company or any Related Entity in accordance with the terms of an Award. None of the Company, its officers or its directors shall have any fiduciary obligation to the Participant with respect to any Awards unless and until the Participant is duly issued Shares pursuant to the Award on the stock books of the Company in accordance with the terms of an Award. Neither the Company, nor any Related Entity, nor any of the their respective officers, directors, representatives or agents is granting any rights under the Plan to the Participant whatsoever, oral or written, express or implied, other than those rights expressly set forth in this Plan or the Award Agreement.

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(i) **Unfunded Status of Awards; Creation of Trusts.** The Plan is intended to constitute an "unfunded" plan for incentive and deferred compensation. With respect to any payments not yet made to a Participant or obligation to deliver Shares pursuant to an Award, nothing contained in the Plan or any Award Agreement shall give any such Participant any rights that are greater than those of a general creditor of the Company or Related Entity that issues the Award; provided that the Committee may authorize the creation of trusts and deposit therein cash, Shares, other Awards or other property, or make other arrangements to meet the obligations of the Company or Related Entity under the Plan. Such trusts or other arrangements shall be consistent with the "unfunded" status of the Plan unless the Committee otherwise determines with the consent of each affected Participant. The trustee of such trusts may be authorized to dispose of trust assets and reinvest the proceeds in alternative investments, subject to such terms and conditions as the Committee may specify and in accordance with applicable law.

(j) **Nonexclusivity of the Plan.** Neither the adoption of the Plan by the Board nor its submission to the stockholders of the Company for approval shall be construed as creating any limitations on the power of the Board or a committee thereof to adopt such other incentive arrangements as it may deem desirable.

(k) **Payments in the Event of Forfeitures; Fractional Shares.** Unless otherwise determined by the Committee, in the event of a forfeiture of an Award with respect to which a Participant paid cash or other consideration, the Participant shall be repaid the amount of such cash or other consideration. No fractional Shares shall be issued or delivered pursuant to the Plan or any Award. The Committee shall determine whether cash, other Awards or other property shall be issued or paid in lieu of such fractional shares or whether such fractional shares or any rights thereto shall be forfeited or otherwise eliminated.

(l) **Governing Law.** Except as otherwise provided in any Award Agreement, the validity, construction and effect of the Plan, any rules and regulations under the Plan and any Award Agreement shall be determined in accordance with the laws of the State of Wisconsin without giving effect to principles of conflict of laws, and applicable federal law.

(m) **Non-U.S. Laws.** The Committee shall have the authority to adopt such modifications, procedures and subplans as may be necessary or desirable to comply with provisions of the laws of foreign countries in which the Company or its Related Entities may operate to assure the viability of the benefits from Awards granted to Participants performing services in such countries and to meet the objectives of the Plan.

(n) **Construction and Interpretation.** Whenever used herein, nouns in the singular shall include the plural and the masculine pronoun shall include the feminine gender. Headings of Articles and Sections hereof are inserted for convenience and reference and constitute no part of the Plan.

(o) **Severability.** If any provision of the Plan or any Award Agreement shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction.

(p) **Plan Effective Date; Termination of Plan.** This Plan will become effective on the Effective Date. It is expressly intended that approval of the Company's shareholders not be required as a condition of the effectiveness of the Plan, and the Plan's provisions shall be interpreted in a manner consistent with such intent for all purposes. Specifically, Nasdaq Stock Market Rule 5635(c) generally requires shareholder approval for stock option plans or other equity compensation arrangements adopted by companies whose securities are listed on the Nasdaq Stock Market pursuant to which stock awards or stock may be acquired by officers, directors, employees or consultants of such companies. Nasdaq Stock Market Rule 5635(c)(4) provides an exemption in certain circumstances for "employment inducement" awards (within the meaning of Nasdaq Stock Market Rule 5635(c)(4)). Notwithstanding anything to the contrary herein, if the Company's securities are traded on the Nasdaq Stock Market, then Awards under the Plan may only be made to Employees who have not previously been an Employee or Director of the Company or a Subsidiary, or following a bona fide period of non-employment by the Company or a Subsidiary, in each case as an inducement material to the Employee's entering into employment with the Company or a Subsidiary. Awards under the Plan will be approved by (a) the Company's Compensation Committee comprised entirely of Independent Directors or (b) a majority of the Company's Independent Directors. Accordingly, pursuant to Nasdaq Stock Market Rule 5635(c)(4), the issuance of Awards and the shares of Stock issuable upon exercise or vesting of such Awards pursuant to the Plan are not subject to the approval of the Company's shareholders. The Plan shall terminate at the earliest of (i)such time as no Shares remain available for issuance under the Plan, (ii)termination of this Plan by the Board or (iii)the tenth anniversary of the Effective Date. Awards outstanding upon expiration of the Plan shall remain in effect until they have been exercised or terminated, or have expired.

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**Exhibit 31.1**

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002 I, Mitchell S. Steiner, certify that:

1.I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

- (a)all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- (b)any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022 February 9, 2023

/s/Mitchell S. Steiner

Mitchell S. Steiner

Chairman, Chief Executive Officer and President

**Exhibit 31.2**

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002, Michele Greco, certify that:

1.I have reviewed this quarterly report on Form 10-Q of Veru Inc.;

2.Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3.Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4.The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a)designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b)designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c)evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d)disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5.The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

(a)all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b)any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 11, 2022 February 9, 2023

/s/Michele Greco

Michele Greco

**Exhibit 32.1**

**Certification of Periodic Financial Report Pursuant to 18 U.S.C. Section 1350**

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Veru Inc. (the "Company") certifies that the Quarterly Report on Form 10-Q of the Company for the quarter ended **June 30, 2022** **December 31, 2022** fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and information contained in that Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: **August 11, 2022** **February 9, 2023**

**/s/Mitchell S. Steiner**

**Mitchell S. Steiner**

**Chairman, Chief Executive Officer and  
President**

Date: **August 11, 2022** **February 9, 2023**

**/s/Michele Greco**

**Michele Greco**

**Chief Financial Officer and  
Chief Administrative Officer**

This certification is made solely for purpose of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose.

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#### DISCLAIMER

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